UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY ADJUDICATION THAT DEFENDANTS DID NOT COMPLY WITH THEIR DUTIES UNDER THE FEDERAL CONTROLLED SUBSTANCES ACT TO REPORT SUSPICIOUS OPIOID ORDERS AND NOT SHIP THEM

(Corrected)

June 28, 2019

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INTRODUCTION

Between 1996 and 2018, Defendants collectively shipped hundreds of millions of dosage units of opioids into Summit and Cuyahoga Counties in fulfillment of orders that, under the Controlled Substances Act ("CSA"), were "suspicious" and should never have been shipped. *See* Ex. 1, Rafalski Report; Ex. 2, McCann Report; Ex. 3, Keller Report. In some instances, for some defendants, these "suspicious order" shipments represented as much as 80% of the total opioid transactions and as much as 92% of the dosage units shipped.

The CSA requires Defendants to maintain effective controls against diversion. Under regulations promulgated by the federal Drug Enforcement Agency ("DEA"), the maintenance of such controls requires Defendants to design and operate systems to identify "suspicious orders" and to report such orders to the DEA when they are discovered. The CSA also requires the Defendants to refrain from shipping orders flagged as "suspicious" unless it has been determined that the order is not likely to be diverted.[1] The undisputed evidence shows that Defendants did none of that. They failed to design serious suspicious order monitoring ("SOM") systems that would identify suspicious orders (defined by the DEA to include orders unusual size, frequency, or pattern); they failed to report suspicious orders to the DEA; and they shipped orders that were, or should have been, flagged as suspicious. Indeed, as detailed below, several of the Defendants have already admitted, in settlements with the DEA, that they did *not* comply with their CSA duties.

The Defendants' dereliction of their CSA duties was staggering: they did not overlook a mere handful of suspicious orders, or miss the occasional order likely to be diverted. They made no effort actually to identify suspicious orders, failed to flag orders that, under any reasonable algorithm, represented between one-quarter and 90% of their business, and kept the flow of drugs coming into

[1] The contours of these duties, and in particular, of the obligation not to ship suspicious orders, is the subject of Plaintiffs' companion Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act, which seeks summary adjudication that the CSA requires registrants to identify, report, and refrain from shipping suspicious orders.

Summit and Cuyahoga Counties. Their failure to identify suspicious orders was their business model: they turned a blind eye and called themselves mere "deliverymen" with no responsibility for what they delivered or to whom. Just like any street drug courier. Unlike the drug couriers to whom they (perhaps unwittingly) compared themselves, however, Defendants had been granted the privilege of dealing lawfully in controlled substances and, in exchange for and as a condition of that privilege, were specifically charged with assisting in enforcement of the CSA and with preventing diversion of the dangerous and otherwise illegal drugs in which they trafficked. Because the Defendants' failure to meet the obligations placed on them was so extreme and so blatant, there is no genuine dispute about their violations of the CSA. This Court can and should find, based on the undisputed evidence, that each of the Defendants repeatedly violated the Controlled Substances Act in their shipments to Summit and Cuyahoga Counties.

LEGAL STANDARD

Rule 56 provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "Summary judgment is proper where the moving party has 'show[n] that there is no genuine dispute as to any material fact and that [they are] entitled to judgment as a matter of law.'" *Humphrey v. Stored Value Cards*, 355 F. Supp. 3d 638, 641 (N.D. Ohio 2019) (*quoting Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). It is "well-established that a court may grant partial summary judgment that establishes the existence of certain facts or liability, even though no actual judgment is entered on a claim." *Brauer v. Pannozzo*, 232 F. Supp. 2d 814, 818 (N.D. Ohio 2002). "Once the movant makes a properly supported motion, the burden shifts to the non-moving party to demonstrate the existence of a genuine dispute." *Pund v. City of Bedford*, 339 F. Supp. 3d 701, 709 (N.D. Ohio 2018). That requires the non-moving party to "produce evidence that results in a conflict of material fact to be resolved by a jury." *Cox v. Ky. DOT*, 53 F.3d 146, 150 (6th Cir. 1995). When deciding whether a genuine issue of material fact exists, the court views the evidence in the light most favorable

to the non-moving party. *Pund*, 339 F. Supp. 3d at 709. "A dispute over a material fact cannot be 'genuine' unless a reasonable jury could return a verdict for the nonmoving party." *Cincinnati Ins. Co. v. Zen Design Grp., Ltd.*, 329 F.3d 546, 552 (6th Cir. 2003).

Rule 56 permits a party to move for summary judgment on a claim or defense or on a "part of [a] claim or defense." Fed. R. Civ. P. 56(a). The rule thus "make[s] clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense." Fed. R. Civ. P. 56, Advisory Committee Notes, subdivision (a) (2010). Courts have recognized that partial summary judgment as to a particular issue is appropriate where it will streamline or shorten the trial and thus serve the interests of judicial economy. *See, e.g., McDonnell v. Cardiothoracic & Vascular Surgical Assocs., Inc.*, No. C2-03-0079, 2004 WL 1234138, at *1 (S.D. Ohio May 27, 2004); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 682, 692 (E.D. Mich. 2000).

UNDISPUTED BACKGROUND FACTS

Defendants Operate in a "Closed System" Designed to Prevent Diversion of Dangerous Narcotics

The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.*, establishes a "closed system" for the manufacture, sale, and distribution of certain drugs, including prescription opioids. This means that "all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion." Ex. 4, Rannazzisi 2006 letter. As the DEA has pointed out, "[i]f the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." *Id.* This responsibility is critical, because "Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people." *Id.*

One of the mechanisms through which the DEA administers the "closed system" is its power to grant, deny, or revoke registration under the CSA. The CSA sets forth as a primary factor in the grant of a registration to manufacture or distribute controlled substances the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C. § 823(a)(1), (b)(1); *see also* 21 C.F.R. § 1301.71(a) ("[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."). Registrants who fail to maintain such effective controls may have their registration revoked, *see Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007). In this way, DEA seeks to ensure that only those who can be trusted to maintain effective controls against diversion are permitted to participate in the supply-chain for controlled substances. The mandate to maintain effective controls against diversion requires that, in exchange for the privilege of dealing in these drugs, registrants must play a substantial role in maintaining the closed-system and ensuring that dangerous drugs are not diverted. The system does not rely on the DEA to police shipments of controlled substances, but rather enlists registrants and requires them, in the first instance, to assume that task. *See Southwood Pharmaceuticals*, 72 FR 36487-01, 36504, 2007 WL 1886484 (the DEA cannot all by itself "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics; it "must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers.").

The DEA requires that, in order to maintain effective controls against diversion, a registrant must design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); report to the DEA suspicious orders "when discovered" (the "reporting duty"); and decline to ship an order identified as suspicious unless, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping

duty"). *Masters Pharmaceutical*, 861 F.3d at 212-213; *see also Southwood Pharmaceuticals*, 72 FR 36487-01, 36500; 21 C.F.R. § 1301.74. "Suspicious orders" include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

Manufacturers, distributors, and pharmacies participate in the supply-chain for prescription opioid drugs, which are categorized under either Schedule II or Schedule III of the CSA. Manufacturers sell and ship these drugs to distributors, subject to the CSA requirements to guard against diversion. This means that, in shipping their products to distributors, opioid manufacturers are required to identify orders from distributors that are "suspicious" within the meaning of the CSA (including whether the orders are of unusual size, frequency, or pattern), report suspicious orders to the DEA, and to refrain from shipping suspicious orders unless the manufacturer determines that the order is not likely to be diverted. *See* § 1301.74; *see also* 21 U.S.C. § 823(a), (d) (requirements for registrants who are manufacturers of Schedule II or Schedule III drugs). The distributors, in turn, sell and ship opioids to pharmacies. They must identify orders from their customers – that is from pharmacies to whom they ship -- that are "suspicious" within the meaning of the CSA (including whether the orders are of unusual size, frequency, or pattern), report suspicious orders to the DEA, and refrain from shipping suspicious orders unless they have determined that the order is not likely to be diverted. *See* § 1301.74; *see also* 21 U.S.C. § 823(b), (e) (requirements for registrants who are distributors of Schedule II or Schedule III drugs). In order to maintain the closed system and guard against diversion, registrants at each step in the supply chain must take steps to ensure that orders they ship are not likely to be diverted. *See* Ex. 4, Rannazzisi 2006 ("all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion.").

As discussed below, *see* pages 14 to 17, the Manufacturers and Distributors had enormous amounts of information available to them about the ultimate destinations of the drugs they shipped.

Despite their protestations to the contrary, Manufacturers had no difficulty discovering where the distributors with whom they dealt shipped their drugs, which doctors prescribed them, and where the prescriptions were filled. Distributors similarly had visibility about the pharmacies to whom they delivered opioids and the doctors whose prescriptions were filled there. But, as discussed below, *see generally* Point II, the Defendants declined to use this information to meet their CSA obligations to maintain effective control against diversion and instead did what they could to keep the flow of opioids moving.

Defendants Understood Their CSA Duties

Defendants well understood their obligations under the CSA. Not only did the DEA remind them, but their own internal documents show an awareness of what they were required to do but consistently failed to do.

Almost immediately after the CSA was enacted, the DEA adopted implementing regulations, including a regulation clearly setting forth the obligations to "provide effective controls and procedures to guard against theft and diversion of controlled substances," to identify suspicious orders, and to report then to the DEA "when discovered." *See* Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 F.R. 7776-7825, 7784-7785 (1971); *see also* 21 C.F.R. § 1301.74. Manufacturers (including, specifically Mallinckrodt), distributors, and their industry associations commented on the regulations before they were officially promulgated. *See* 36 F.R. at 7776-78. In 1984, Acting Chief of the DEA's Diversion Operations Section, Thomas Gitchel, wrote to the National Wholesale Druggists Association ("NWDA" – a predecessor to the Distributors' current industry association, the Healthcare Distribution Alliance ("HDA") – further explaining the duties of registrants and, in particular, stating that "the submission of a monthly

printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders" and that "DEA has interpreted 'orders' to mean prior to shipment."[2]

On September 27, 2006, in response to a "serious and growing health problem in this country," Joseph Rannazzisi, the Deputy Assistant Administrator in DEA's Office of Diversion Control, sent a letter to every commercial entity in the United States registered with the DEA to distribute controlled substances to "reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces." Ex. 4, Rannazzisi 2006. Rannazzisi's 2006 letter set forth in no uncertain terms the duty to identify suspicious orders, to inform the DEA "of suspicious orders when discovered by the registrant," and to "avoid filling suspicious orders that might be diverted. . . ." *Id.* The letter set forth 14 "Circumstances That Might Be Indicative of Diversion" as identified by the DEA and urged distributors to consider these circumstances in evaluating orders. *Id.*

On December 27, 2007, Mr. Rannazzisi sent a second letter, this one addressed to "every entity in the United States registered with the Drug Enforcement Administration (DEA) to *manufacture or distribute* controlled substances." Ex. 6, Rannazzisi 2007 letter (emphasis added). The purpose of the letter was to "reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders." *Id.* The letter reminded manufacturers and distributors alike of their obligation to "inform the local DEA Division Office of suspicious orders *when discovered* by the registrant." *Id.* (emphasis in original). The 2007 letter further explained:

> Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders *prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.* Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

[2] *Id.* at CAH_MDL_PRIORPROD_DEA07_00869974, Ex. 5 (emphasis added).

. . .

> [R]egistrants that routinely report suspicious orders, yet fill these orders *without first determining that order is not being diverted* into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion.

Ex. 6, 2007 Letter (emphasis added). The 2007 letter also called the attention of the Manufacturers and Distributors to the administrative decision in *Southwood Pharmaceuticals* and in particular to the discussion in that decision of the obligation "to report suspicious orders when discovered by the registrant, and . . . .your obligation to maintain effective controls against the diversion of controlled substances." *Id.* The 2006 and 2007 DEA letters thus clearly and undisputedly put the defendants – both manufacturers and distributors – on notice of their obligations under the CSA.

In addition, many of the Defendants have *admitted* that they knew what their CSA obligations were. For example, Teva witnesses have acknowledged that during the entire period Teva sold Schedule II opioid products, the company had a duty equal to that of the wholesale distributors to monitor and stop suspicious orders and to investigate the downstream orders of customers. Teva witnesses further acknowledge that the DEA letters from 2006 and 2007 set forth its duties to monitor and stop suspicious orders; the witnesses testified that they did not have any disagreement with the statements in the letters. *See* Ex. 7, McGinn Dep. pp. 110-131; 136-137; 175-176; 386-389; Att. 3, Ex. 8, Tomkiewicz Dep. pp. 174-203.

For its part, Cardinal acknowledges that it was advised of its obligations. Not only was Cardinal aware of the 1984 DEA letter, it also acknowledges that it received, around 1990, guidelines prepared by the NWDA titled "NWDA Suspicious Order Monitoring System." Those guidelines explained:

> Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders. DEA has interpreted "orders" to mean prior to shipment.

In 2003, Cardinal obtained a copy of the 1996 DEA Diversion Investigators Manual from the DEA pursuant to a Freedom of Information/Privacy Act request.[3] The manual sets forth the responsibilities of diversion investigators, and, according to DEA's 30(b)(6) designee Thomas Prevoznik, was the "official policy of the DEA as of 1996."[4] The manual states

> Registrants, who routinely report suspicious orders, yet fill these orders, with reason to believe they are destined for the illicit market, *are expressing an attitude of irresponsibility that is a detriment to the public health and safety as set forth in 21 U.S.C. 823 and 824*.[5]

The manual also describes registrants' responsibility to halt shipment of suspicious orders:

> An investigation will be conducted for possible violation of the CSA and regulations upon determining that the reporting registrant, *as a general practice, does not voluntarily halt shipments of controlled substances to registrants involved in suspected diversion* or to registrants against whom previous action has been taken. *In these instances, the registrant is subject to the appropriate prosecution and/or administrative action.*[6]

Although Cardinal had the DEA Diversion Investigators Manual since 2003, its Rule 30(b)(6) designee, Jennifer Norris, nonetheless testified that Cardinal became aware of the no-shipping requirement when it received the DEA's 2006 letter reminding registrants of their duty to stop shipment of suspicious orders.[7] But regardless of the precise date, Cardinal has acknowledged that it understood its responsibilities no later than September 2006.

McKesson, too, has admitted it was well aware of its duties under the CSA. One of McKesson's 30(b)(6) witnesses, Nate Hartle, testified to his understanding that since 1970 McKesson had a duty under the CSA to prevent diversion through its monitoring of controlled substances. (*See* Ex. 12, 7/31/18 Hartle Depo. at 78:4-10; 85:2-9). McKesson's monitoring program acknowledged its duties to report suspicious orders and to halt shipment of any orders that are deemed suspicious.

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[3] *See* Ex. 9, CAH_MDL2804_02203353.

[4] *See* Ex. 10, Deposition of DEA 30(b)(6) (Thomas Prevoznik), Vol. II, 693:4-697:12.

[5] *See* Ex. 9, CAH_MDL2804_02203353, 02203356-7 (emphasis added).

[6] *Id.* at 02203357 (emphasis added).

[7] *See* Ex. 11, Depo. of Norris, 171:20-172:1; 173:23-174:4.

(*See* Ex. 12, 7/31/18 Hartle Depo. at 36:14-37:4; 38:5-19). Further, McKesson has conceded that violations of these CSA requirements result in a substantial and detrimental effect on the health and general welfare of the American people. (*See* Ex. 12, 7/31/18 Hartle Depo. at 43:22-44:5).

In addition to the above, the evidence shows that HDA members, particularly the distributors, were aware of and, in fact, were working to address "DEA expectations of wholesale distributors to take action on suspicious orders."[8] In that regard, the distributors knew that DEA "expect[ed] more than just reporting 'suspicious orders,'" and that upon identifying a suspicious order, distributors should "either stop the delivery or should evaluate the customer further before delivering it."[9] They also knew that "[s]imply complying with the 'suspicious orders' regulatory requirement does *not* mean, in the [DEA]'s view, that the registrant is maintaining an effective program to detect and prevent diversion."[10] Based on the guidance received from the DEA, the HDA, working with distributors and manufacturers through the Pain Care Forum, compiled a set of industry compliance guidelines ("ICGs") that were prepared "in recognition of the growing problem of misuse of Controlled Substances and the key role distributors play within the prescription drug supply chain."[11] In the ICGs, the industry also recognized that through "due diligence, it is possible to reduce the probability that controlled substances will reach locations within the supply chain for which they are not

[8] Ex. 517, HSI-MDL-00620224 at 620225-26.

[9] Ex. 518, CAH_MDL2804_02489199.

[10] *Id.* Notably, HDA members were also aware that the DEA expected registrants "know their customers," and were given examples of the way to conduct due diligence investigations, including the kinds of information registrants should be considering. *Id.* at 02489200.

[11] Ex. 519, HDA_MDL_000148603; Ex. 520, HDA_MDL_000148607. Notably, HDA's members participated in the creation of the ICGs and received copies of the ICGs and of the notes about DEAs comments to the ICGs before voting to approve them through the Executive Committee. *See* CAH_MDL2804_0249160; Ex. 410, HDA_MDL_000151104; Ex. 409, HDA_MDL_000150198; Ex. 408, HDA_MDL_000139414; HDA_MDL-000213181; Ex. 406, HDA_MDL_000213212; Ex. 404, HDA_MDL_000213229; Ex. 397, HDA_MDL_000148603; Ex. 403, HDA_MDL_000213058; CAH_MDL2804_01521412 ("I've attached a copy of the very latest version of the draft suspicious order practices. The Executive Committee approved these, but indicated that HDMA should continue to work with the Regulatory Affair Committee and other relevant staff on the details."); Ex. 402, HDA_MDL_000213078; Ex. 401, HDA_MDL_000145918; Ex. 399, HDA_MDL_000081363; Ex. 398, HDA_MDL_000081364.

intended."[12] While the HDA's members claimed that they "have always recognized and followed requirements that registrants identify and report 'suspicious orders,'" the ICGs were "[b]ased on the expertise and strong endorsement of [HDA's] members" and developed "for meeting and exceeding DEA's expectations."[13]

To that end, distributors, through their HDA representatives, participated in a meeting with the DEA, which was led by HDA's outside counsel from Williams & Connolly ("W&C").[14] During this meeting, the W&C lawyers presented the ICGs to the DEA on behalf of HDA's members, and with respect to suspicious orders, were asked by DEA, "what is stopped"?[15] In response, on behalf of HDA's members, the W&C lawyers explained that under the guidelines, distributors were expected to stop the entire order of the specific product that exceeded a threshold, and further explained that HDA "intended to help [its] members implement the guidelines by making consultants known to them that could aid in implementation," and would "discuss [the ICGs] with the pain Care Forum."[16]

Subsequently, another meeting occurred where the HDA received DEA's specific feedback on the guidelines.[17] The HDA's summary of this meeting documents the DEA's specific requests to the HDA and its members. Highlighting the shipping requirement, the DEA wanted an entire section added to the body of the ICGs about the topic.[18] When discussing monitoring for suspicious orders, the DEA explained that "an electronic system is not enough, [registrants] can't rely solely on a

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[12] Ex. 397, HDA_MDL_000148607.

[13] *Id.* at 148608. The draft of the ICGs circulated by the HDA to its members contains many guidelines surrounding the regulations that the Defendants claim were unclear including, for example, the requirement to "Stop Shipments of an Order of Interest." *Id.* at148612.

[14] Ex. 396, CAH_MDL2804_02489188. The Williams & Connolly lawyers are identified in this meeting as Bob Barnett and Rich Cooper.

[15] *Id.* at CAH_MDL2804_02489189.

[16] *Id.*

[17] Ex. 393, CAH_MDL2804_02489191. Notably, Williams & Connolly lawyers were present for this additional meeting with the DEA. *Id.*

[18] *Id.*

computer system."[19] According to HDA, "DEA seemed to want something else done, *that was not after-the fact*, that was not electronic, and that would identify problems very quickly, as the orders occurred."[20] "DEA seemed to think that 'thresholds' focus principally on volumes, and they expressed the view that an exclusive or even principal focus on volume is inadequate."[21] Furthermore, the DEA specifically requested that the ICGs state that "[t]he drug or drugs that cause an order to be an order of interest should not be shipped the order is an order of interest," and further explained that "DEA has backed away from the standard of three times the monthly overage order for schedule II and ARCOS reportable schedule III products. DEA suggested that we [HDA] substitute a paragraph based on more recent DEA guidance."[22]

The DEA asked the HDA to emphasize "that the order should not be shipped if there was reason to believe there was a problem. In fact, they asked [HDA] to add in that if one controlled substance in the order could be a problem, then other controlled substances in the order may also be a problem and the distributor should consider holding the others."[23] DEA also explained that "[e]ven an order for a drug that does not meet a volume threshold may be suspicious in light of other aspects of the order."[24] Critically, DEA emphasized that "suspicious orders mmust [*sic*] be reported toi [*sic*] to DEA whether the wholesaler ships or not, and [told HDA] to emphasize that the timeliness of notice is very important."[25] HDA's memo about the DEA's guidance closes with a number of other significant points, including the following:[26]

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[19] *Id.* at 2489192.

[20] *Id.*

[21] *Id.*

[22] *Id.* at 2489193.

[23] *Id.* at 2489194.

[24] *Id.*

[25] *Id.* at 289195.

[26] *Id.*

- "DEA was emphatic that if there were questions about an order, the order *should not* be shipped."
- "They [DEA] wanted reports on all 'suspicious orders' *even if the order was not shipped*."
- "Timeliness was very important. DEA wants us [HDA] to emphasize the need for rapid, timely reporting."
- "DEA wants reports of 'suspicious orders' even if there is some question about the dispenser's status as a customer. For example, if during a background check of a potential customer, the customer indicates they might be placing orders that could be 'suspicious', DEA wants to know, even if the pharmacy in question, does not become a customer."

The undisputed evidence shows that Walgreens, too, well understood its CSA obligations. In September 2007, three of Walgreens's senior employees attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas.[27] Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." [28] During this meeting, Mr. Mapes also advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."[29]

The DEA affirmed again its expectation that the "Do Not Ship" requirement applied to all orders flagged as being potentially suspicious, whether called "suspicious orders" or "orders of interest", in the Compliance Addendum to the June 2013 Memorandum of Agreement ("MOA")[30] between Walgreens and the DEA, which included the following clause:

> For purposes of complying with suspicious order monitoring and reporting requirements for orders to be supplied by a Walgreens distribution center . . . Walgreens will endeavor to conduct its evaluations of "orders of interest" identified by its tolerance thresholds and ceiling limits within four (4) business days in most cases, and shall inform DEA Field Offices of orders that Walgreens has determined are

[27] Ex. 13, CAH_MDL_PRIORPROD_DEA07_01185382 at CAH_MDL_PRIORPROD_DEA07_01185404-5.

[28] Ex. 14, CAH_MDL_PRIORPROD_DEA_12_00011059; Ex. 15, HDS_MDL_00002032 at 2040.

[29] Ex. 16, Acquired_Actavis_00441354 at 441355.

[30] Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, "Walgreens 2013 MOA") (Ex. 17, WAGMDL00490963-WAGMDL00490978; Ex. 18, WAGMDL00387975-WAGMDL00387982; Ex. 19, WAGMDL00387653-WAGMDL00387974)

> "suspicious" within two (2) business days of making any such determination. Walgreens agrees not to ship any "order of interest" or "suspicious order" in whole or in part unless and until Walgreens resolves the reason(s) that caused it to designate the order as an "order of interest" or a "suspicious order."[31]

PSI also was aware of the "no-shipping requirement" and recognized that it was part of PSI's obligations since the enactment of the CSA.[32]

Manufacturers and Distributors Alike Have a Wealth of Information Available to Them about the Orders They Ship, the Pharmacies to Which Opioids Are Delivered, and the Doctors Who Prescribe These Drugs

Because of the nature of the "closed-system," Defendants operated their opioid businesses in a data-rich environment. Every opioid shipment from a manufacturer to a distributor had to be documented; every opioid shipment from a distributor to a pharmacy had to be documented; every opioid that was dispensed by a pharmacy had to be dispensed pursuant to a prescription. Moreover, this data was collected and made available to the Defendants to help them run their business and increase their profits. Thus, Manufacturers knew what they shipped to each Distributor and Distributors knew what they shipped to each pharmacy. But in fact, Defendants had a great deal more information than that.

Defendants had access to several different types of data. Each Distributor kept track of inventories and total sales of each manufacturer's products; this data is referred to as "852 data." Distributors also had so-called "867 data," which broke out sales to their downstream customers by zip code and type of outlet. But Distributors weren't the only ones who had access to 852 and 867 data. Through fee-for-services and other similar arrangements, the Distributors sold the 852 and 867 data to the Manufacturers, which allowed the Manufacturers to see the flow of their drugs further down the supply chain.[33] Distributors and Manufacturers also entered into "chargeback" agreements

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[31] Walgreens 2013 MOA (Ex. 17, WAGMDL00490963-WAGMDL00490978; Ex. 18, WAGMDL00387975-WAGMDL00387982; Ex. 19, WAGMDL00387653-WAGMDL00387974) at WAGMDL00490978

[32] Ex. 20, Deposition of Thomas Schoen, 59:11-60:2.

[33] *See* Ex. 191, [JAN-MS-01117436]; Ex. 234.

pursuant to which Manufacturers agreed to reimburse Distributors if Distributors were unable to re-sell the drugs they had purchased at a particular price.[34] In order to claim "chargebacks," Distributors had to provide Manufacturers with details about their shipments to their downstream customers, including pharmacies, hospitals, and other dispensers. The Distributors provided chargeback data to the Manufacturers on a daily basis. Through the chargeback data, the 852 data, and the 867 data, which included drug, dosage, and package quantity, Manufacturers had access to information regarding the purchasing patterns of their customers' customers. They were able to analyze the data and see the size, pattern and frequency of most orders of their drugs delivered to retail pharmacies and other dispensers. Moreover, to the extent that Manufacturers sold their drugs to multiple Distributors, they were able to see purchasing and prescribing patterns through multiple channels. They could see, for example, that particular pharmacies received their products through multiple distributors.

The Defendants also had access to information about prescriptions through "Xponent data" that they could purchase through IQVIA (formerly known as IMS). IQVIA Xponent data provides information on every opioid prescription filled, tracking the doctor who wrote the prescription and the drug prescribed. Manufacturers purchased this information from IQVIA in order to assess their own sales efforts. They could track precisely which doctors were prescribing their drugs and tailor their marketing efforts accordingly. IQVIA data was the lynchpin of the Manufacturers' marketing efforts and, in particular, of the compensation scheme for their sales representatives. Without the detail in the IQVIA data, the Manufacturers would not have been able to tell which sales representatives were most effective at their jobs, because they would not have known which doctors were writing the prescriptions reflected in their sales. Together with the 867 data and chargeback data, the IQVIA Xponent data allowed the Defendants to see both sides of the downstream transactions

[34] *See* Ex. 191, [JAN-MS-01117436]; Ex. 226; Ex. 235, ENDO-OPIOID_MDL-01056072.; Ex. 74, Seid Dep. Dec. 12, 2018 at 80:11-82:16

involving their drugs: the shipment from the Distributor to the pharmacy, and the dispensing of prescriptions written by identified doctors.

Defendants could also purchase additional data about prescriptions from Pharma Centra. For example, Pharma Centra was able to provide Endo with detailed information about the reasons particular pharmacies had refused to fill individual prescriptions. *See.* [ENDO_OPIOID_MDL_00468003-004]. Manufacturers also received data about the use of Patient Savings Cards, cards that entitled patients to discounts at the drug store. When a customer used a Patient Savings Card in connection with an opioid purchase, information about the transaction was sent to the Manufacturer so that the pharmacy could be reimbursed for the discount.

In combination, the available data provided Manufacturers and Distributors with powerful tools for marketing and for monitoring the supply-chain for opioids. The various data streams gave Defendants who wanted it nearly complete visibility about where the opioids they sold ended up. Defendants were also able to, and did, hire outside vendors to assist them in analyzing the wealth of data they received.[35]

Defendants knew about to use this data to detect suspicious orders, but as described below, almost uniformly declined to do so. On March 13, 2012, for example, Robin Abrams, Vice-President and Associate General Counsel at Purdue, gave a presentation at an HDMA conference in Orlando, Florida. The slide-deck from this presentation shows that Ms. Abrams outlined for the HDMA members in attendance precisely how to use fee-for-service data (e.g., 867 data), IMS (IQVIA) data, and information from a company's own sales force for their order monitoring systems. Ex. 87, [Abrams presentation]. The presentation points out that sharing data gathered within a company on the sales side – "prescriber programs" that focus on doctors' prescribing patterns – and on the SOM

[35] *See, e.g.,* Ex. 74, Seid Fact Dep. 138:15-139:20; Ex. 191, JAN-MS-01117436 ("Based on purchasing behavior, we can now identify the most valuable individual pharmacies in the marketplace"); *see also* Ex. 547 (noting that ValueCentric provides "end-to-end data visibility from the manufacturer to the patient.")

side – which focuses on pharmacies and ordering patterns – can assist in detecting diversion. The presentation notes that sharing of this "signal detection information "[e]nables us to consider prescriber and pharmacy issues within particular geographic areas." *Id.* It is clear then, that Manufacturers and Distributors alike were able to monitor where opioids were actually being dispensed and detect patterns suggestive of diversion.

Additionally, because the self-distributing Pharmacy Distributors had a vertically integrated structure, these Distributors in particular had complete visibility into all dispensing level data from their own pharmacies.

SOM Programs

Suspicious order management ("SOM") programs are the means by which Manufacturers and Distributors carry out (or should carry out) their duties under the CSA. In order to be effective, such programs "should be documented as a standard operating policy for the company and be distributed to all relevant employees." Ex. 1, Rafalski Report Section M; *see also* Ex. 21, Whitelaw Report. In order to maintain effective controls against diversion, a SOM policy must begin with vetting new customers. To this end, a registrant should have "a comprehensive system in place and conduct an investigation on a customer who will be purchasing controlled substances." *Id.* Factors that may be relevant to investigation of a new customer include: whether the customer has a business plan in place that demonstrates the legitimacy of the business and provides for compliance with the CSA; past history of DEA registration and compliance history; state and local licensure compliance; compliance history with state medical/pharmacy board; affiliation with pain management doctors; percentage of controlled substance business; other distributors providing control substances; percentage of cash payments and insurance payments; pharmacy utilization reports; on-site inspection of customer; and internet search to determine any negative information. *Id.*; *see also* Ex. 21, Whitelaw Report.

Even when customers have been vetted, a SOM policy must identify whether particular orders from a customer are suspicious. As noted above, under DEA regulation, the term "suspicious orders"

includes orders of unusual size, unusual frequency, and/or unusual pattern. 21 C.F.R. § 1301.74; *see also* Ex. 1, Rafalski Report at Section M; Ex. 21, Whitelaw Report. Although there are numerous ways to design an effective SOM system, certain factors are integral to the detection of suspicious orders. These factors include the type of customer and the scope of medical practice; proper identification of drugs, to identify products with higher risk of diversion; thresholds based on the amount of controlled substances required by a legitimate customer with a similar business and business model; population of the region served and frequency of orders being filled from out-of-state; density of the region at issue; patterns of ordering, both as industry information on the most frequently prescribed drug, as well as combinations of drugs, and frequency of orders. Ex. 1, Rafalski Report Section M. The system incorporating these factors should include a procedure and criteria for setting threshold quantities; a procedure for adjusting threshold quantities; justifications for changes to thresholds, including analysis of historical orders from the customer, the physician patient population served by the customer and on-site customer review; compliance review; proper management of the role of the sales department; identification of the person(s) responsible for reporting suspicious orders to the DEA; and sufficient due diligence review and documentation to ensure that orders identified as suspicious but subsequently shipped have been properly cleared. *Id.*; *see also* Ex. 22, Kinsey Expert Report at 8. Although Defendants' SOMs experts insist that registrants have discretion to design their own SOM programs, and that there is no one-size-fits-all program, they do not materially disagree that all of the above factors are all relevant to the determination of whether a particular order is "suspicious."

Suspicious order management is part of a larger context of corporate compliance. *See* Ex. 21, Whitelaw Rep. at 5-7. Corporate compliance programs have been developed in the context of the Federal Sentencing Guidelines for Organizations ("FSG"), which set penalties for corporate malfeasance and criminal conduct, and provide incentives for corporations to implement effective compliance programs. *Id.* Comments to the FSG as originally issued established seven criteria for

effective compliance programs; the existence of such effective compliance programs is a factor in corporate sentencing, encouraging corporations to establish compliance programs in accordance with these criteria. The seven elements of effective compliance programs include established compliance standards and procedures; specific individuals with responsibility to oversee compliance; due care in the delegation of responsibility; effective communication of compliance standard and procedures to employees; reasonable steps, including monitoring and auditing systems, to achieve compliance, consistent enforcement; and, when an offense is detected, reasonable steps to respond appropriately. *See* U.S. Sentencing Commission, Guidelines Manual, § 8A.1.2, comment. (n. 3k) (Nov. 1991); Ex. 21, Whitelaw Report at 7-8. Updates to the FSG have expanded the discussion, and increased the importance, of corporate compliance to the sentencing guidelines, meaning that corporations that fail to maintain effective compliance programs are treated more harshly in the assessment of criminal responsibility. *See* Ex. 21, Whitelaw Rep. at 9-10. Because the manufacture or distribution of controlled substances other than as authorized by the CSA constitutes criminal conduct, *see* 21 U.S.C. § 841; *see also* below at Point I, the FSG standards are relevant to the level of criminal responsibility a corporation may bear for violations of the CSA.

Because there are numerous ways to operate an effective SOM program, Plaintiffs have identified several different models that would identify suspicious orders based on the unusual size criteria alone, though these models are necessarily over narrow as they do not account for all of the other disjunctive criteria for identifying suspicious orders." These models include "Maximum Monthly, Trailing 6 Month Threshold," "2x Trailing 12 Month average," "Extraordinary Order Method – 3x Trailing 12 Month Average," "Maximum 8,000 Dosage Units Monthly," "Maximum Daily Dosage Units," "McKesson 8,000 Rule," and "Maximum Monthly, Trailing Six-month Threshold (also known as "Common Sense"). *See* Ex. 1, Rafalski Report; Ex. 25, McCann Report; Ex. 3, Keller Report. As discussed below, the undisputed evidence shows that consistent application of

any of these systems alone would have identified thousands of suspicious orders in the relevant time period. Yet, as discussed below, Defendants consistently failed to identify more than a handful of suspicious orders and failed to report and halt shipment of suspicious orders in the relevant time period.

ARGUMENT

I. PARTIAL SUMMARY ADJUDICATION ON DEFENDANTS' COMPLIANCE WITH THEIR CSA DUTIES WILL STREAMLINE THE TRIAL

Partial summary judgment with respect to Defendant's compliance with the CSA duties wills streamline the trial. Although Plaintiffs do not assert any claim under the CSA, Defendants' violation of that statute is relevant to several of the claims Plaintiffs do assert. As described herein, a finding from this Court that Defendants manufactured and/or shipped opioids in violation of the CSA has consequences for particular elements of many of Plaintiffs' claims.

A. Adjudication that Defendants Violated Their CSA Duties Will Streamline the Presentation of Plaintiffs' RICO Claims at Trial

Adjudication that Defendants violated their CSA duties will streamline Plaintiffs' presentation of their RICO Claims. The federal RICO statute makes it unlawful for "any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity. . . ." 18 U.S.C. § 1962. "'[P]attern of racketeering activity' requires at least two acts of racketeering activity, . . . the last of which occurred within ten years (excluding any period of imprisonment) after the commission of a prior act of racketeering activity." 18 U.S.C. § 1961(5). Accordingly, the elements of a civil RICO claim are: (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity, and (5) injury to the plaintiff's business or property by reason of the violation. *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 496 (1985); *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 404 (6th Cir. 2012); *see also* 18 U.S.C. § 1964. Summary adjudication that Defendants have violated the CSA will satisfy the "pattern of racketeering activity"

elements of Plaintiffs' RICO claims, obviating the need for Plaintiffs to prove these elements at trial, and allowing the parties to concentrate on the remaining elements of the claims.

The RICO statute defines "racketeering activity" to include "any offense involving . . . the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substances Act), punishable under any law of the United States. . . ." 18 U.S.C.A. § 1961(1)(D). Defendants' conduct, described in detail below, constitutes two separate types of felonious violation of the CSA.

The CSA provides that, "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally - to manufacture, distribute, or dispense a controlled substance . . . ." 21 U.S.C. § 841(a). Thus, *all* manufacture and distribution of controlled substances than is not authorized by the CSA is unlawful. The regulations promulgated pursuant to the CSA define the scope of what the statute authorizes. *See U.S. v. DeBoer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (rejecting challenge to conviction under § 841 based asserted vagueness of the statute, because DEA regulation sufficiently defined defendant's responsibilities); *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (upholding conviction under § 841 based on standards found in applicable regulations); *United States v. Hayes*, 595 F.2d 258, 259 (5th Cir. 1979) ("The purpose of [DEA] regulation is to define the circumstances in which a physician or pharmacist who is registered to dispense controlled substances may nevertheless be held to have violated the proscription against manufacturing, distributing or dispensing a controlled substance contained in 21 U.S.C. § 841); *see also United States v. Moore*, 423 U.S. 122, 134 (1975) (rejecting argument that "registrants" cannot be prosecuted under § 841). Accordingly, it is clear that manufacture or distribution in violation of regulations may constitute a violation of § 841.

Moreover, § 841 provides for strict penalties, including lengthy prison terms, for the unlawful manufacture or distribution of Schedule II or Schedule III drugs. 21 U.S.C. § 841(b)(1)(C)

(prescribing penalty of up to 20 years in prison for violations involving Schedule I or Schedule II drugs), § 841(b)(1)(E) (prescribing penalty of up to 10 years in prison for violations involving Schedule III drugs). The opioid drugs at issue here are, or at relevant times were, classified as either Schedule II or Schedule III drugs. *See* 21 U.S.C. § 812. The penalties prescribed are sufficient to demonstrate that these offenses are "felonious" and thus qualify as RICO predicate acts.[36]

Defendants violated at least two separate provisions of the CSA, such that their manufacture or distribution of Schedule II or Schedule III opioids was felonious.[37] First, as described in detail below, Defendants manufactured and distributed opioids without maintaining "effective controls against diversion." *See* 21 C.F.R. § 1301.74. This included failing to design and operate a system for identifying suspicious orders, failing to report suspicious orders to the DEA, and/or failing to halt suspicious orders pending investigation to determine whether diversion was likely. These violations of § 1301.74 rendered Defendants' manufacture and distribution felonious under § 841.

In addition, the CSA also makes it unlawful to "furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept or filed under the [CSA]." 21 U.S.C. § 843(a)(4)(A). As this Court previously recognized, "furnishing false information as alleged may constitute concealment."[38] To the extent that, as described below, Defendants failed to report to the DEA orders they knew or should have known were suspicious, they either furnished false information or omitted material information from the reports they provided. Similarly, to the extent that Defendants reported suspicious orders, but

[36] Indeed, the recent criminal conviction of several Insys executives confirms that violations of § 841 constitute RICO predicate acts. The executives were convicted under the RICO statute; the verdict form demonstrates that violations of the CSA were among the predicate acts on which some of those convictions were based. Ex. 23. Moreover, the criminal complaint confirms that violations of § 841 formed a portion of the government's case. Ex. 24.

[37] It is not unduly harsh to recognize Defendants' unlawful conduct for what it was – illicit drug dealing "under the patina of legitimate authority." *See Southwood Pharmaceuticals,* 72 FR 36487-01, 36500, 2007 WL 1886484. That is precisely how the DEA described the conduct of the pharmacies to whom Southwood Pharmaceuticals distributed hydrocodone and on account of which it lost its registration.

[38] Report & Recommendation at 46. Plaintiffs' reserve their right, at trial and in post-trial motions, to submit evidence and argue that the RICO Defendants were aware of and refused to report suspicious orders.

omitted from their reports the fact that the suspicious orders had been shipped without any due diligence investigation, their reports again omitted material information.

As described below, the undisputed evidence shows that Defendants violated the CSA – and thus unlawfully manufactured and distributed controlled substances – not once or occasionally, but repeatedly and habitually. Their violations were systemic, occurring over and over again. Although the DEA may deem "substantial compliance" with its regulations, rather than "strict compliance," to be sufficient, *see* 21 C.F.R. § 1301.71, the evidence shows that Defendants' failures to meet their obligations were so pervasive as to preclude a finding that they were in "substantial compliance." For this reason, the undisputed evidence establishes both the "pattern" and the "racketeering activity" required for Plaintiffs' RICO claims.

B. Adjudication that Defendants Violated Their CSA Duties Will Streamline the Presentation of Plaintiffs' Nuisance and Negligence Claims at Trial

Determination that Defendants' violated the CSA is also important for, and will streamline the trial with respect to, Plaintiffs' nuisance claims. Both Plaintiffs bring claims for statutory public nuisance. *See* Summit TAC at Count Five; Cuyahoga TAC at Count Five. As to Summit, this claim was upheld by Magistrate Judge Ruiz [Doc. 1025 at 66-68] and this Court. [Doc. 1203 at 30-31]. Under Ohio law, nuisances are defined as including that "declared by statutes to be a nuisance." O.R.C. § 3767.01(C)(1). The Ohio Revised Code further provides that the "violation by a... person of any laws of Ohio or of the United States of America... controlling the distribution of a drug of abuse... is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance." O.R.C. § 4729.35. Opiates are "a drug of abuse". O.R.C. §§ 3719.01(R), 3719.011. The CSA and its implementing regulations are "laws... of the United States of America" controlling the distribution of opioids which are a "drug of abuse." *See* 21 U.S.C. §§ 801-971 (2006); 21 C.F.R. §§ 1300-1321 (2009). Undisputed violations of the CSA set forth herein constitute a nuisance under O.R.C. §§ 3767.01(C)(1), 3719.01(R), 3719.011, 4729.35. Because there is

not a factual dispute over whether the Defendants violate the CSA, it would be an unnecessary waste of trial time detailing the evidence of those violations set forth herein.

Similarly, Defendants' violations of the CSA are also significant to Plaintiffs' common law absolute public nuisance claims. Both Plaintiffs bring this claim. *See* Summit TAC at Count Six; Cuyahoga TAC at Count Six. Under Ohio common law, a public nuisance is "an unreasonable interference with a right common to the general public" and an "unreasonable interference includes... conduct that is contrary to a statute, ordinance, or regulation." *Cincinnati v. Beretta U.S.A. Corp.*, 2002-Ohio-2480, ¶¶ 8-9, 95 Ohio St. 3d 416, 418–19, 768 N.E.2d 1136, 1142 (quoting Restatement (Second) of Torts, § 821B). Claims of "statutory or regulatory violations involving public health or safety," are common examples of conduct constituting a common law public nuisance. *Cincinnati v. Beretta, supra.* The CSA violations proven here are violations of law which constitute an unreasonable interference with public rights under the Section 821B test in *Cincinnati v. Beretta supra.* Like the statutory public nuisance claims, presentation of the evidence of the Defendants' undisputed CSA violations is unnecessary here, and the trial can be streamlined if this Court grants this motion.[39]

The CSA violations also play a key role in Plaintiffs other common law claims. For example, regarding Plaintiffs' negligence claims, [*see* Summit TAC at Count Seven; Cuyahoga TAC at Count Seven] the CSA and its implementing regulations provide a standard of care for the underlying common law duty by establishing how a reasonable manufacturer or distributor of dangerous drugs would and should behave under the circumstances.[40] And, as for Plaintiffs' conspiracy claims, [*see* Summit TAC at Count Eleven; Cuyahoga TAC at Count Eleven], this Court has found that the same

[39] In addition, Defendants also claim that their activities alleged were sanctioned by law which is defense to a common law nuisance claim. *See* Doc. 491-1 at 29-30 and Doc. 499-1 at 44-45. This defense is not available when Defendants' conduct actually is contrary to the law supposedly sanctioning it. *See* Doc. 654 at pp. 11-12. Thus, resolving the issue of CSA compliance will remove the need for evidence on this defense at trial.

[40] *See Eisenhuth v. Moneyhon*, 119 N.E.2d 440 (Ohio 1954) (holding legislative enactments, including administrative rules, and judicial decisions may establish a standard by which defendant's duty is measured); *see also Kooyman v. Staffco Constr. Inc.*, 937 N.E.2d 576 (Ohio Ct. App. 2010) (violation of an administrative rule may establish standard); *Chambers v. St. Mary's Sch.*, 697 N.E.2d 198 (Ohio 1998) (violation of an administrative rule is admissible as evidence of negligence); Stephens v. A-Able Rents Co., 654 N.E.2d 1315 (Ohio Ct. App. 1995) (regulations are admissible as bearing on violations of duty).

illegal conduct constituting a statutory public nuisance would state a claim for civil conspiracy. Doc. 1203 at p. 21. The trial of these claims would be also be streamlined by this Court granting partial summary judgment that the Defendants' conduct violated the CSA and its implementing regulations.

II. THE UNDISPUTED EVIDENCE SHOWS THAT, AS A MATTER OF LAW, DEFENDANTS FAILED TO COMPLY WITH THE CSA WITH RESPECT TO OPIOID ORDERS SHIPPED INTO SUMMIT AND CUYAHOGA COUNTIES

As set forth in Plaintiffs' Memorandum in Support of Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act ("CSA Duties Mem."), in exchange for the privilege of manufacturing and/or distributing controlled substances, Defendants are required by law to provide "effective controls and procedures to guard against theft and diversion of controlled substances." *See* CSA Duties Mem. at 3; *see also* 21 U.S.C. § 823; 21 C.F.R. § 1301.74. In order to provide such controls, Defendants must design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders so identified (the "reporting duty"); and to decline to ship an order identified as suspicious unless, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty"). *Masters Pharmaceutical,* 861 F.3d at 212-213; *see also Southwood Pharmaceuticals,* 72 FR 36487-01, 36500,. *See generally* CSA Duties Mem.

The evidence that Plaintiffs have gathered shows that there is no genuine issue of fact as to whether Defendants violated the CSA; rather, the undisputed evidence shows that each of the Defendants repeatedly and consistently manufactured, sold, and/or shipped opioids in violation of their CSA obligations. This evidence includes Defendants' internal documents concerning their SOM programs; Defendants' communications with the DEA; and Plaintiffs' expert report analyzing the Defendants' SOM programs and their compliance with the CSA. *See* Ex. 1, Rafalski Report; Ex. 25, McCann Report; Ex. 21, Whitelaw Report; Ex. 3, Keller Report. It also includes admissions by Cardinal, McKesson, Walgreens, Mallinckrodt, and CVS that they failed to comply with their CSA obligations. Together, this evidence shows that Defendants failed to maintain effective controls

against diversion, either because they failed to design and operate a system for identifying suspicious orders, because they failed to report suspicious orders to the DEA, and/or because they failed to halt shipments of suspicious orders pending investigation. As described below, in some instances, or for some time periods, Defendants had no system in place for detecting suspicious orders; in others, Defendants had a system but did not follow it (thus breaching their obligation to "operate" their system). In some instances, Defendants failed to report any suspicious orders, or any meaningful number of such orders to the DEA. For others, or during other time periods, Defendants failed to halt shipment of orders pending investigation. The evidence also shows that DEA repeatedly found that Defendants were not complying with their legal duties. *See,e .g.* Ex. 10, Prevosnik Dep. Based on this evidence, no reasonable factfinder could conclude that Defendants substantially complied with their CSA obligation to maintain effective controls against diversion. For this reason, the Court can and should rule, as a matter of law, that Defendants failed to comply with their duty under the CSA to "maintain effective controls against diversion."

A. Mallinckrodt Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Between 2006 and 2014, more than 2.3 billion (2,363,328,618) morphine-milligram equivalents ("MMEs") of opioids manufactured by Mallinckrodt (including its subsidiary, SpecGx) were sold in Summit and Cuyahoga counties, representing approximately 25% of the total quantity of opioids dispensed during that period. McCann Second Supplement at 4. Attributing suspicious orders shipped by distributors to Summit and Cuyahoga Counties to the manufacturers who made the drug, between 26.2% and 92% of the Mallinckrodt MMEs shipped in Summit and Cuyahoga Counties were part of suspicious orders, depending on the SOM metric applied. *Id.* at 9-19. Put another way, Mallinckrodt's customers were routinely shipping suspicious orders, and substantial portions of Mallinckrodt's business depended on that fact. Among Mallinckrodt's distributor customers were Harvard Drug Group, Keysource, Masters Pharmaceutical, Kinray, and Value Drug, all of whom shipped substantial

amounts of Mallinckrodt products and ultimately had their licenses revoked by the DEA. *See* Ex. 26, S. Becker Deposition Ex. 33 (June 15, 2010) (DEA Press Release re Harvard's suspension); Ex. 27, S. Becker Deposition Ex. 36 (Sept. 15, 2015) (DEA Notice of Decision & Order re Masters); Ex. 28, S. Becker Deposition Ex. 38 (Jun. 10, 2011) (Press Release re KeySource license suspension); Ex. 29, S. Becker Deposition Ex. 37 (Dec. 23, 2016) (DOJ Press Release re civil penalty levied against Cardinal); Ex. 30, S. Becker Deposition Ex. 35 (Jun. 25, 2014) (DOJ Press Release re Value Drug settlement). As shown below, Mallinckrodt's failure to detect that significant amounts of its opioid products were being shipped under circumstances indicative of diversion was the entirely predictable consequence of Mallinckrodt's failure to maintain controls against diversion, to operate an effective SOM program, and to halt shipments to questionable customers.

1. Mallinckrodt has admitted that it failed to maintain effective controls against diversion

Mallinckrodt has already admitted, in an agreement with the U.S. Department of Justice and the Drug Enforcement Administration, that it failed to maintain effective controls against diversion. *See* Ex. 31, Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration, Mallinckrodt plc and Mallinckrodt LLC (July 10, 2017) ("AMOA"). In 2011, the DEA commenced a multi-year investigation into Mallinckrodt's failure to maintain effective controls against diversion.[41] Based on this investigation, the DEA alleged that Mallinckrodt "sold excessive amounts of the most highly abused forms of oxycodone, 30 mg and 15 mg tables, placing them into a stream of commerce that would result in diversion." Ex. 31, AMOA at 1.[42] According to the DEA, "even though Mallinckrodt knew of the pattern of excessive sales of its oxycodone feeding massive diversion, it continued to incentivize and supply these suspicious sales," and "never notified the DEA of the suspicious orders in violation of the CSA." *Id.*

[41] Ex. 32, John Gillies 30(b)(6) Deposition at 239:8-11 (Feb. 7, 2019) (the formal DEA investigation began in September 2011).

[42] Indeed, the DEA had previously identified Mallinckrodt as the "kingpin within the drug cartel" in a meeting between DEA and Mallinckrodt in July 2010. *See* Ex. 548.

The DEA's investigation identified numerous failures by Mallinckrodt to maintain effective diversion controls, including a failure to (a) "conduct adequate due diligence of its customers," (b) "detect and report to the DEA orders and unusual size and frequency," (c) "detect and report to the DEA orders deviating substantially from normal patterns" – including "orders that purchased a disproportionate amount of a substance which is more often abused compared to other products," (d) use "chargeback information from its distributors to evaluate suspicious orders," and (e) "take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers." *Id.* at 2-3. At the conclusion of this investigation, and in lieu of an enforcement action against its DEA registrations, Mallinckrodt agreed that from January 1, 2008, through January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007." *Id.* at 3-4, *see* Exs. 4, 6.[43]

Mallinckrodt's expert, Ronald Buzzeo, opines that Mallinckrodt's admissions of failure to comply with the CSA are not legally binding, *see* Ex. 35, Buzzeo Report at 36-37. This legal opinion is insufficient to create an issue of fact about whether Mallinckrodt complied with the CSA.[44]

2. Mallinckrodt's SOM Program was primarily based on a threshold formula

From its inception, the Mallinckrodt SOM program was based on a threshold formula that compared the size of orders from distributors against the average size of previous orders for either a 12- or 18-month time period. *See* Ex. 34, K. Harper Deposition at 83:24-84:3 (prior to 2003, the SOM program consisted of "an algorithm and some other factors."); *see also* Ex. 36, J. Rausch Deposition at 194:3-10 (the algorithm was part of the computer code for the order entry system, known as JD

[43] *See also* Ex. 34, Harper Depo. Tr. 453:15-454:6.

[44] Mr. Buzzeo also contends that Mallinckrodt's SOM program as designed was compliant, but does not assess how Mallinckrodt actually implemented it or whether Mallinckrodt ever identified or halted suspicious orders. Again, Mr. Buzzeo's failure to offer opinions on these topics prevents his opinion from creating a genuine issue of material fact.

Edwards or JDE, an Enterprise Resource Planning ("ERP") software platform). According to Mallinckrodt's written policies—the first of which was drafted in 2008—Mallinckrodt initially used a 2x multiplier relative to the prior 12-month average in its formula. *See* Ex. 37, Mallinckrodt DEA Compliance Procedure, Controlled Substance Suspicious Order Monitoring, Draft 2 (May 13, 2008). However, Mallinckrodt later increased this formula to a 3x multiplier to reduce the number of peculiar orders identified because of the amount of orders it had to review. Ex. 34, K. Harper Depo. 321:11-25 (justifying moving from a 2x to 3x formula because the peculiar order report was "too lengthy" and was creating too much of an "administrative burden"). This threshold formula was the foundation for Mallinckrodt's SOM program: if an order did not exceed the threshold set by Mallinckrodt's numeric formula, it was not flagged as "peculiar" and therefore not examined at all. *See* Ex. 36, J. Rausch Depo. at 194:3-23 (confirming that if an order was not flagged by Mallinckrodt's algorithm, it was not examined, and acknowledging that if there were gaps or faults in the algorithm, it was possible for problematic orders to get through); Suspicious Order Monitoring Program No. C/S Comp 3.0, (Oct. 29, 2010) Ex. 38, MNK-T1_0000264260 (establishing threshold for identifying "peculiar" orders and setting forth procedure for reviewing and classifying peculiar orders as "suspicious" and elevating these orders to DEA report status).

According to the DEA, Mallinckrodt's own compliance department, and an independent consultant Mallinckrodt retained to review its SOM program, Mallinckrodt's reliance on rigid numeric formulas was inconsistent with maintaining effective controls against diversion. The DEA's 2007 letter had made clear to Mallinckrodt and other registrants that relying on rigid formulas was insufficient:

> Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the

> distributors. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviated from the normal pattern of what pharmacies generally order.

Ex. 39, Rannazzisi Letter (Dec. 27, 2007), MNK-T1_0007146632; see also Ex. 32, J. Gillies 30(b)(6) Dep. Tr. at 74:17-23 (testifying that Mallinckrodt knew by the date of this letter that adherence to a rigid formula was inadequate to detect suspicious orders).

The DEA's concerns were echoed by Mallinckrodt's own compliance department. Ex. 36, J. Rausch Deposition at 194:3-23 (agreeing that if Mallinckrodt's algorithm was faulty or had gaps that it was possible that problematic orders could get through); Ex. 34, K. Harper Deposition at 203:1-17 (acknowledging that releasing an order without conducting an investigation or performing due diligence meant that the order could potentially be suspicious); *see also* Ex. 40, SOM Team Activity Log at 3, MNK-T1_0000477889 (quoting an email from Cathy Stewart in July 2009 "[w]e need to investigate and make sure they're not just gradually increasing their order quantities to not get caught by the 2X formula threshold."). In addition, Howard Davis, a former DEA employee retained by Mallinckrodt to specifically evaluate its SOM program, was sharply critical of Mallinckrodt's reliance on a formula (what Mallinckrodt referred to as an "algorithm"), and even went so far as to state that by doing so, Mallinckrodt "would be unnecessarily exposing itself to potential liability." Ex. 41, Memorandum from Howard Davis to Karen Harper, Suspicious Order Monitoring Program No. C/S Comp 3.0, (Nov. 2, 2010), MNK-T1_0000269399. In short, Mallinckrodt was well aware—from multiple sources—that relying primarily on a rigid formula was inadequate, but it chose to do so anyway.

3. Mallinckrodt's SOM program failed to detect suspicious orders and report them to the DEA

Between 2003 and 2011, Mallinckrodt shipped more than 53 million orders of opioid products. During this time period, Mallinckrodt's SOM formula—such as it was—identified 37,817 orders as potentially suspicious (or "peculiar" in Mallinckrodt's terminology). But in this same period,

Mallinckrodt appears to have stopped—at most—33 orders and reported them to DEA. These numbers speak for themselves: it is inconceivable that at the height of the opioid crisis, Mallinckrodt encountered only 33 suspicious orders out of 53 million. These numbers are unsurprising, however, in light of the evidence regarding Mallinckrodt's implementation of its SOM program.

First, it is undisputed that Mallinckrodt shipped orders *prior* to completing the due diligence on those orders. *See* Ex. 42, Email from James Rausch to Karen Harper and George Saffold Re Suspicious Order Monitoring Program (June 9, 2010), MNK-T1_0000279153; *see also* Ex. 34, Harper Dep. Tr. 199:24-200:10, (admitting that Mallinckrodt "did not always perform due diligence on peculiar orders before shipping them"). Shipping orders without due diligence in and of itself indicates a failure to maintain effective controls against diversion, and is in direct violation of DEA guidance from the December 27, 2007 Rannazzisi letter. Ex. 39, MNK-T1_0007146632 While Mallinckrodt claims that it determined, after the fact, that none of these orders were suspicious, this convenient coincidence cannot constitute effective diversion controls. Mallinckrodt's director of compliance, Karen Harper, conceded that the failure to complete due diligence prior to shipping the order meant that suspicious orders could have been shipped. *See* Ex. 34, K. Harper Deposition at 203:1-17. Just as drunk driving is clearly reckless regardless of whether anyone is injured, shipping potentially suspicious orders is clearly contrary to maintaining effective diversion controls, regardless of whether any of the orders are ultimately deemed likely to be diverted.

Second, maintaining effective controls against diversion also requires, at a minimum, identifying orders of unusual size, frequency, or that deviate substantially from normal patterns. Ex. 39, Rannazzisi Letter (Dec. 27, 2007), MNK-T1_0007146632. Nevertheless, both Mallinckrodt's internal communications and witness testimony demonstrate that from 2008 through 2009, Mallinckrodt's suspicious order monitoring program consisted *solely* of verifying DEA 222 forms—i.e., verifying that the customer had a valid DEA registration and had accurately notified the DEA of

the order. Ex. 43, Email from Karen Harper to John Adams *et al.* Re Suspicious Order Monitoring Training Notes from Bulk Narcotic Sales Meeting Presentation (Jun. 6, 2008), MNK-T1_0000419956; *see also* Ex. 36, J. Rausch Deposition at 139:14-140:9 (other than verification of the 222 forms Mallinckrodt did not have a suspicious order program in place between fall of 2008 and 2009). In other words, during the 2008-2009 time period, Mallinckrodt discontinued use of its threshold formula and completely failed to evaluate whether the orders it was filling were of unusual size, frequency, or deviated substantially from normal patterns. Mallinckrodt's former director of security, William Ratliff, acknowledged that this practice—relying solely on DEA 222 forms—was inadequate. *See* Ex. 44, W. Ratliff Deposition, 242:2-9 (Dec. 19, 2018) (agreeing that it would not be proper to rely solely on registration status and the 222 form in determining whether to ship an order).

Finally, the sales force—the national account managers ("NAMs") responsible for generic opioid sales—were given key roles in investigating and clearing suspicious orders. According to Karen Harper, the NAMs were supposedly the "eyes and ears and boots on the ground" for the compliance department. *See* Ex. 34, K. Harper Deposition at 59:15-16. But this assignment of roles and responsibilities ignored that the compensation scheme for NAMs was weighted heavily to favor sales over compliance. The bonuses for NAMs were largely based on sales volume, and could exceed six figures for productive account managers. *See* Excel Spreadsheet showing National Account Manager bonus payments, Ex. 45, MNK-T1_0000315995. In contrast, there is nothing in the record indicating that NAMs were evaluated based on their compliance responsibilities, or that NAMs were ever penalized for failing to stop suspicious orders. In fact, NAMs were viewed by some employees as "advocates" for their distributor customers, as opposed to watchdogs with a responsibility for stopping diversion. *See* Ex. 46, K. Neely Deposition at 354:21-355:21. Moreover, Mallinckrodt understood this conflict. *See* Ex. 47, Meeting Notes from Buzzeo Conference (Oct. 27-30, 2008), MNK-T1_0000302097 (reporting the "general consensus is that sales reps are not considered a good

option for on-site investigations and initial review prior to accepting new customers due to their perceived bias in getting the customer approved for sales revenue purposes"); Ex. 48, Email from Karen Harper to Eileen Spaulding Re SOM (Sept. 24, 2010), MNK-T1_0000280260 (noting the "conflict of interest" in having sales personnel involved in determining which orders to ship). Despite awareness that industry standard was to remove sales personnel from SOM decision-making roles due to this conflict, Mallinckrodt continued to give NAMs the authority to clear orders. *See*, *e.g.*, Ex. 47, MNK-T1_0000302097 (Buzzeo industry conference notes); Ex. 49, MNK-T1_0001521990, Ex. 50, MNK-T1_0000290934 (examples of NAMs clearing orders in 2011 and 2012).

Regardless of how Mallinckrodt's SOM program was supposed to function in theory, the evidence demonstrates that in practice Mallinckrodt's reliance on its sales force was contrary to its obligation to maintain effective controls against diversion. There are numerous examples of Mallinckrodt clearing suspicious orders for shipment based on weak justifications provided by the NAMs to the compliance department. Example of such rationales include:

- That a customer was an "established customer," (Ex. 51, Email from Bill Ratliff to James Rausch *et al.* Re Propoxyphene Napsylate orders for Sovereign (Sept 3, 2008), MNK-T1_0000290520);
- That a distributor customer had a new downstream customer that would be ordering a lot of oxycodone, (Ex. 52, Email from Steven Becker to Karen Harper *et al.* Re Old Bridge account (Oct. 28, 2008)), MNK-T1_0000448888);
- That a customer had expanded its customer base to other states, (Ex. 53, Email from Victor Borelli to Kate Muhlenkamp (Nov. 14, 2008), MNK-T1_0000290502 (noting that new Sunrise Wholesale sales manager is "extremely tied into the Florida market");
- That the NAM wanted to keep the "momentum rolling" with a customer, (Ex. 54, Email from Victor Borelli to James Rausch Re Peculiar order report (Mar. 23, 2010), MNK-T1_0000297371);
- That a customer needed to increase its order volume in order to secure favorable pricing, (Ex. 55, Emails from Steven Becker to Penny Myers and James Rausch Re HD Smith (May 5, 2010), MNK-T1_0000298906);
- That a wholesaler customer's split order of oxycodone (12,720 bottles on July 1st and 12,720 bottles on July 2nd) was attributable to higher demand for oxycodone at the beginning of the month and that customer had shown

"extremely large growth [] on all items, especially this one," (Ex. 56, Email from Victor Borelli to Brenda Rehkop *et al.* (Jun. 23, 2010), MNK-T1_0000560555 (in response to Rehkop asking, "Do you know why they are ordering so much oxy? We need an answer that will satisfy the DEA, in [case] they have questions in the future.");

- That a customer's inability to obtain opioids from another source justified filling an order many times above historical levels, (Ex. 57, Email from Bill Ratliff to Kate Muhlenkamp *et al.* Re Oxycodone orders (Jun. 4, 2008), MNK-T1_0000562682).

Mallinckrodt's reliance on its NAMs to help implement its SOM program is particularly problematic given their cavalier attitude towards Mallinckrodt's compliance obligations. One of their most highly compensated NAMs, Victor Borelli, engaged in a telling email exchange with one of his distributor contacts at Key Source Medical, Steve Cochrane, after Mr. Cochrane had received an overnight shipment of 1200 bottles of oxycodone from Mallinckrodt. Mr. Cochrane wrote: "Keep'em comin'! Flyin' out of here. It's like people are addicted to these things or something. Oh, wait, people are . . ." Mr. Borelli responded: "Just like Doritos keep eating. We'll make more." Ex. 58, Email Chain Between Victor Borelli and Steve Cochran Re Oxy 30 (Jan. 27, 2009) (emphasis added), (MNK-T1_0000559532.) This is the same NAM who would tell customer service representatives "anything they want to hear just so he can get a sale," as one of the Customer Service Managers, Cathy Stewart, warned the Director of Compliance and the Director of Security. *See* Ex. 59, Email from Cathy Stewart to Bill Ratliff and Karen Harper Re Sunrise Wholesale (May 20, 2008), MNK-T1_0000290611.[45]

Steven Becker, another highly compensated NAM, repeatedly testified during his deposition that he had access to information on problematic distributors, but never reviewed any of it. Ex. 67,

[45] Mr. Borelli himself once described his job using the phrase "ship, ship, ship," and emailed a distributor client asking them to check their inventories and "[i]f you are low, order more. If you are okay, order a little more. Capesce?"; and joked that the distributor should "destroy this e mail… Is that really possible? Oh Well…." *See* Ex. 60, Email from Victor Borelli to Steve Cochrane, Re. things (May 20, 2008), MNK-T1_0000506535.

The distributors in question all received substantial amounts of Mallinckrodt products and ultimately had their licenses revoked by the DEA. Ex. 26, S. Becker Deposition Ex. 33 (June 15, 2010) (DEA Press Release re Harvard's suspension); Ex. 27, S. Becker Deposition Ex. 36 (Sept. 15, 2015) (DEA Notice of Decision & Order re Masters); Ex. 28, S. Becker Deposition Ex. 38 (Jun. 10, 2011) (Press Release re KeySource license suspension); Ex. 29, S. Becker Deposition Ex. 37 (Dec. 23, 2016) (DOJ Press Release re civil penalty levied against Cardinal); Ex. 30, S. Becker Deposition Ex. 35 (Jun. 25, 2014) (DOJ Press Release re Value Drug settlement).

4. Mallinckrodt failed to use reasonably available chargeback data despite the fact that such data

Mallinckrodt's failure to maintain adequate controls against diversion is particularly egregious given the detailed information that it possessed, in the form of chargeback data, regarding where its products were going. As Karen Harper explained, chargeback data "tells Mallinckrodt exactly which pharmacy to which the drugs were sold, what the DEA registration number is, the pharmacy address, the quantity, and which drugs they have sold to that pharmacy." Ex. 34, K. Harper Deposition at 227:13-18. As noted above, the NAMs also had access to this data, which essentially gave Mallinckrodt visibility into the entire supply chain for its products, from manufacturer to distributor to pharmacies and other end users. *See, e.g.*, Ex. 61, V. Borelli Deposition at 130:5-136:24; Ex. 67, S. Becker Deposition at 158:13-18, 161:24-163:1. Using this data would have allowed Mallinckrodt's compliance department to see that many pharmacies and pain clinics, particularly in Florida, were purchasing opioids from multiple distributors, a red flag for diversion. *See* Ex. 62, G. Collier Deposition at 197:6-11 & Ex. 63, Collier Ex. 15 (Nov. 11, 2010 email between G. Collier, S. Becker, and V. Borelli, MNK-T1_000418885) & Ex. 64, Collier Ex. 16 (Sept. 2010) (Summary of customers sourcing more than 2 distributors for Oxy 30, MNK-T1_000418885). Chargeback data would also have revealed that Harvard, one of Mallinckrodt's distributor customers, was doing business as a vet supply company (First Veterinary Supply), and had supplied 12,487 orders of Oxy 15 and Oxy 30 to doctors, 92.4% of

which went to the state of Florida. *See* Ex. 67, S. Becker Deposition at 190:4-192:19 & Ex. 15). This data would also have allowed Mallinckrodt to identify problem pharmacies that had been cut off by certain Mallinckrodt distributors, and make sure that these pharmacies did not continue to receive Mallinckrodt products from other Mallinckrodt distributors. By way of example, in October 2010, one of Mallinckrodt's distributors, Masters, had identified and cut off a problematic pharmacy (Brooks Pharmacy). Notwithstanding this action, Brooks continued to receive Mallinckrodt products because Cardinal, another Mallinckrodt distributor, continued to supply them – in fact, Cardinal appears to have increased its shipments of opioid products to Brooks in response to the Masters shut-off. *See* Ex. 65, Harper Exhibit 29 (Oct. 20, 2011 email from Wayne Corona to Karen Harper re cut-off pharmacies, MNK-T1_0000311741); Ex. 34, K. Harper Deposition at 417:20-419:12; *see also*, Ex. 66, Harper Exhibit 30 (Brooks Pharmacy Monthly Total 15mg & 30mg Oxy "Sales Qty Govt UOM" 2010-2011, MNK-T1_0001519959 & MNK-T1_0001810303).

Mallinckrodt's chargeback data goes as far back as 1998. *See* Ex. 68, MNK-T1_0007965587-7965588 (chargeback data for 1998-2018 produced by Mallinckrodt in this litigation). But Mallinckrodt's compliance department did not begin to consider specifically utilizing chargeback data until 2007, and the compliance department did not start evaluating that data until 2009-2010, despite the relative ease in which MNK could access and evaluate this data. *See* Ex. 69, email from Karen Harper to herself (Nov. 18, 2010), MNK-T1_0000280835 (Harper notes indicating that she was currently working on adding chargeback data analysis to the SOM program); Ex. 34, K. Harper deposition at 355:22-356:22 and Ex. 70, Karen Harper Ex. 21 (MNK-T1_0007728295 (Harper admits that in April 17, 2007 email chain, she understood that chargeback data could be used to identify end purchasers of Mallinckrodt pills); Ex. 34, K. Harper deposition at 360:11-365:10 (Harper admits that she was told it would be easy to access chargeback data, and that the compliance department was

offered to be trained on how to access this data by certain employees at Mallinckrodt, but that she did not take up this offer).

B. Purdue Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Purdue failed to comply with its CSA duties in that it failed maintain and operate a system to identify suspicious orders, failed to use the data it had available to it to identify suspicious orders, failed to report suspicious orders to the DEA, and failed to stop shipments of suspicious orders pending investigation.

Four years after the introduction of Oxycontin in 1996, Purdue created its first suspicious order monitoring system. Recognizing, in 2000, that it was "[r]equired by the DEA to have such a system in place," Purdue drafted its first suspicious order standard operating procedure (SOP), and placed the burden of identifying suspicious orders on their National Accounts department, Ex. 72. Purdue received internal warnings that "National Accounts primary function is to sell, not police orders." Ex. 72. Purdue received the additional internal warning that National Accounts "receives data that is a month old," and any review "would be well after the shipment . . . [and] there is no real time data available to [National Accounts] so that [they] might participate in the decision process to release an order." *Id.* Despite the warnings, Purdue's suspicious order monitoring system was eventually designed to alert Steve Seid, Executive Director of National Accounts & Trade Relations, in the "event orders [were] out of normal parameters" to approve or deny the shipment of any suspicious orders. Ex. 73. Until 2009, Steve Seid was the only person responsible for determining whether suspicious orders should be released, and in 2009 Purdue added just one more individual to assist in deciding if orders should be released. Ex. 74 & Ex. 75.

The system Purdue put in place was, in any event, wholly inadequate to guard against diversion. The suspicious order monitoring system is a part of Purdue's Finance & Accounting SOPs. Purdue's

SOP 7.7 creates a system to disclose suspicious orders of controlled substances, and lists as considerations in determining whether or not to release an order the following factors:

> The explanation for the order received from the customer; The customer's existing credit line; Purdue's credit line insurance limits; The customer's payment history; and, Any recent business developments that may have arisen since the customer's last credit review.

Ex. 88 (PPLPC004000119321). Thus, the focus of the system was on financial considerations, not on the prevention of diversion.

The application of a financially motivated suspicious order monitoring system allowed Purdue to justify releasing a suspicious orders placed by Anda totaling $3,432,000 one of which was "$2,050,000 with a very significant order of 80 mg product." Ex. 77. Although Anda had "operated successfully with an $800,000 line of credit," for two years the orders were released because Anda was "part of Watson they are okay financially and [Purdue] can justify a $5.0mm exposure." Ex. 77. Purdue's Executive Director of National Accounts & Trade Relations, Steve Seid, had responsibility to release orders flagged as suspicious, and in his due diligence for the Anda orders he was informed merely that "Anda had seen a rise in demand particularly at the Ohio facility" with 80mg having averaged 200-300 in the November to February period per month jumping to 425 in April and 876 in March. Ex. 77. As the person solely responsible for releasing or stopping orders flagged as suspicious, Steve Seid not only approved the release of suspicious orders but did so very quickly. Ex. 74, Ex. 75, Ex. 78, Ex. 79, Ex. 80, Ex. 81, Ex. 82, Ex. 83 and Ex. 84.

Outside of its so-called "suspicious order monitoring system," however, Purdue had the information it needed to identify and halt suspicious orders before they were shipped. Purdue entered into agreements with distributors called either Fee for Service Agreements (FFS) or Distribution Service Agreements (DSA), whereby Purdue paid its distributors to provide chargeback data and 852/867 data. (Ex. 85, PPLPC004000344802; Ex. 391, PPLP003430436; Ex. 391, PPLP003430439; and PPLPC00400317962). Chargeback data and 852/867 data provide details of the sales and

distribution of Purdue's opioids from the distributor to individual pharmacies, hospitals and other dispensers. (Ex. 85, PPLPC004000344802; Ex. 391, PPLP003430436). More specifically, through the FFSs and DSAs Purdue received the data of what Purdue's customers had sold to their customers. Ex. 89. Through chargeback data, which included drug, dosage, and package quantity, Purdue had access to information regarding the purchasing patterns of their customers' customers. Purdue conducted weekly reconciliations with the chargeback data. Ex. 90 and Ex. 91. Purdue used ValueTrak to analyze the chargeback data, which gave Purdue visibility of the size, pattern and frequency of most orders of Purdue's opioids delivered to retail pharmacies and other dispensers. Ex. 74.

Because of the FFS and DSA agreements, Purdue had 93% visibility of its opioids to the pharmacies receiving OxyContin. Ex. 92. Although Purdue's visibility varied at times it was first 93%, at other times 97%, but it was always 90% or better. Ex. 92 and Ex. 93. Using the visibility provided by chargeback data, Purdue instituted SOP 007 in 2009. Ex. 92. SOP 007 created a system of collecting chargeback data as well as data from IMS/IQVIA, and notes and emails, and generating reports for review by the Order Monitoring System (OMS) committee every quarter. Ex. 94.

In addition to dosage and sales data, the OMS committee had access to savings card information, which allowed the committee to see individual prescribers whose prescriptions were being filled at particular pharmacies. Ex. 94. Although the savings card information did not always show the volume of prescriptions filled for an individual prescriber, it did indicate to Purdue which prescriptions were filled for "Region 0" prescribers at a particular pharmacy. Ex. 94. Region 0 prescribers were prescribers suspicious enough that Purdue's sales forces was prohibited from calling on them. *Id.*; Ex. 288, PPLP004035073-7; Ex. 96. As early as 2002, Purdue was evaluating suspicious prescribers on a monthly basis using Xponent data. Ex. 96. The top 200 prescribers were evaluated to determine outliers based on an increase of prescriptions of more than 50% in the current six-month history versus the previous six-months, if more than 25% of prescriptions are paid for with cash or

more than 75% of prescriptions are for either 40mg or 80 mg strengths of OxyContin. Ex. 96. Between savings card information and Xponent data, Purdue was able to create a list of Region 0 prescribers who were "considered to be potential diverters." Ex 74 and Ex. 75. But Purdue did not report these potential diverters or do anything to cut off their supply of opioids.

Pursuant to SOP 007, suspicious orders would be flagged as a result of algorithms applied to the chargeback data received from Purdue's authorized distributors concerning approximately 42,000 to 50,000 pharmacies, dispensers and other outlets. Ex. 93. Of all customers of any of Purdue's distributors, it appears that as of 2012, 365 were reviewed for referral to the DEA. Ex. 93 and Ex. 87. Of the 365, 290 were reported in May of 2011 in an attempt to market OxyContin's new "tamper-resistant" formulation. Ex. 87. Those 290 pharmacies reported to the DEA comprised "all outlets with at 50% decline and $350,000 in annual sales" of OxyContin post-reformulation. Ex. 87.

Regardless of what it reported, however, Purdue shipped the orders in any event. Mark Geraci, the Vice President and Chief Security Officer from 2009 to present, could recall only one instance in which an order was cut of blocked due to size, frequency or pattern. Ex. 97.

C. Teva Failed to Comply with Its CSA Duties to Maintain Effective Controls Against Diversion

As of September, 2012, Teva had *no* written suspicious order monitoring system in place, and had, to the point, never had one. Ex. 35. Indeed, prior to 2012, Teva had never reported a suspicious order to the DEA. In 2012, apparently concerned about heightened DEA vigilance and inspection of the opioid distributors' SOM systems, Teva hired Ronald Buzzeo and Cegedim to perform a review of Teva's SOM system. Their September 2012 report is starkly critical, calling Teva's existing SOM system "rudimentary" and noting, among other things, Teva had no written SOM procedures in place, and had not reported a single suspicious order up to that point. Ex. 98.

Ultimately, Teva decided not to hire Buzzeo or any other third party consultant to design and operate the SOM system, but rather decided to do it in house. Their purported reason was that Buzzeo

had a cloud-based system, and that Teva had concerns about security of the system. The main reason, however, appears to have been to save on costs. Ex. 99. Instead, in early 2013, Teva hired Kevin Kreutzer from AmerisourceBergen to run its SOM program and design a new system. Kreutizer was quickly fired, after just 90 days, when he contacted a downstream customer about a potentially suspicious order. Ex. 100. Teva next hired Joe Tomkiewicz in January 2014, also from AmerisourceBergen, to design Teva's program, even though he does not even have a college degree. Ex. 8. Tomkiewicz testified that just before joining Teva, he had been visited at his home by DEA agents on two occasions, where they advised him to get a lawyer presumably with regard to an investigation they were conducting into AmerisourceBergen's SOM program and opioid diversion. Tomkiewicz also interviewed with the U.S. Attorney's office in Philadelphia the month he joined Teva, but he professed at his deposition he did not remember details about the DEA visits or the interview. Ex. 8.

Tomkiewicz ultimately designed an SOM program which he coined "DefOps," which means "Defensible Operations," which Tomkiewicz admitted was named that way because it was intended to be a system defensible to keep Teva out of trouble with the DEA and because it "sounded good." Ex. 8. The written SOPs for the system were approved in August 2014, nearly two years after the Buzzeo report stated Teva needed to have written procedures in place. Ex. 101, Ex. 102, Ex. 103, Ex. 104, Ex. 105, Ex. 106, Ex. 107, Ex. 108, Ex. 109 and Ex. 110. The biggest flaw with the SOPs is that they kept the key investigatory role in the hands of Teva's Sales Department, which directed customer service to contact the customer for initial investigation and to gather information, and to send a sales rep to the customer if the response was not satisfactory. Ex. 101. The conflicts are apparent from the Plaintiffs' rationale above as to why design of the SOM system was kept in-house, and were readily admitted by Tomkiewicz's 2017 powerpoint on Teva's system which references the sales department under the slide titled "Managing Conflicts." Ex. 111.

Teva's parent company in Israel, Teva Pharmaceuticals Industries Ltd., audited Teva's DEA compliance department in 2015 and prepared a report critical of the department and the SOM program. Ex. 112. The report stated that Teva investigated 10,000 line orders per month of Schedule II products; of these 10,000 orders, 95% were automatically released. Only 5% of the orders were placed on hold to be manually checked. Ex. 8. The report found the DEA Department was in "non-compliance with DEA requirements" and was at "High Risk" of DEA regulatory action, and the SOM program was at "Moderate Risk" for such action. Ex. 112. For the SOM program, the report focused primarily on the fact that suspicious orders were cleared through the decisions of a single person (Tomkiewicz), which exposed the system to the risk of mistaken releases. Ex. 112.[46] The audit noted that the SOM program is must clear 5000 pending potentially suspicious line orders per month under pressure from the sales department to clear those orders quickly so as not to disrupt their customers' opioid supply chain. That number probably more than doubled after the 2016 acquisition of the Actavis generic business from Allergan. Plaintiffs have found no attempt by Teva to obtain verification or an audit from any SOM or other trained outside consultant verifying the design and operation of their SOM system. It is noteworthy the Teva Ltd. auditor did not interview anyone from customer service or the sales department, despite their critical role in interfacing directly with the customers during any investigation of pended SOs.

The inadequacy of Teva's system is confirmed by the fact that even after implemented a written SOMs policy, it reported and stopped very few suspicious orders. Teva report its first ever suspicious order to the DEA on February 13, 2013. It was an order from a small distributor called Capital Wholesale Drug. Ex. 113. The suspicious order report states that the order quantity is not within the customer's normal purchasing pattern, yet fails to elaborate on the customer's historic purchasing quantity. The report provides virtually no information about the SO, nor does it offer to

[46] Tomkiewicz narrowly interpreted the report to require a person to stand behind him to determine whether he was clicking the right button in clearing the order. (Ex. 8, Att. 3, Tomkiewicz Dep. pp. 329-335)

provide any information from Teva's investigation, its findings or the reasons the order was suspicious. This uninformative report is typical of all reports Teva submitted to the DEA.

From 2013 through 2016, moreover, Teva reported only 6 suspicious orders out of 600,000 total line orders (and not all were opioid products). Ultimately, Teva's SOM program reported .00001% of all line orders it was processing. For 2017, Tomkiewicz claimed at least 18 SOs were reported in 2017, but only five such reports are supported by documentary evidence. Ex. 111. Similarly, for 2018, Tomkiewicz testified he reported "close to 50" suspicious orders, but only 15 reports are documented. Ex. 8, Ex. 111, Ex. 114, Ex. 116. Teva reported even fewer suspicious opioids involving opioid products and even fewer involving Schedule II drugs, which in theory should call for the highest levels of scrutiny.

D. The Endo Defendants Failed to Comply with Their CSA Duties to Maintain Effective Controls Against Diversion

The Endo Defendants include Endo Pharmaceuticals, Inc. ("Endo"), Qualitest Pharmaceuticals ("Qualitest"), Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. and its wholly-owned subsidiary, Par Pharmaceutical, Inc. (together, "Par"). Endo was founded in 1997.[47] Its initial portfolio included Percocet (immediate release oxycodone/APAP pills), as well as Numorphan (IV form of oxymorphone).[48] Endo later added generic Oxycontin, which it sold from 2005 to 2006, and Opana/Opana ER (oral oxymorphone, immediate and extended release versions), which it sold from 2006 to 2017.[49]

In 2012, Endo discontinued its original formulation of Opana ER "for safety reasons" because it "was subject to both intentional and inadvertent abuse and misuse."[50] Endo claimed that its

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47 Ex. 117 [Campanelli Dep. at 28:9-11].

48 Ex. 118 [Macrides Dep. Ex. 4]; Ex. 119 [Macrides Dep. at 122:10-12, 127:21 – 134:2]; Ex. 117 [Campanelli Dep. at 44:6 – 45:10].

49 Ex. 117 [Campanelli Dep. at 370:15 – 372:5]; Ex. 120 [Walker Dep. at 482:4-12]; Ex. 118 [Macrides Dep. Ex. 4].

50 Ex. 121; Ex. 122 [Walker Dep. Ex. 23 (E0734) at p. 1].

reformulated version of Opana ER, launched that same year, was safer than its original reformulation because it was "designed to be crush resistant[.]"[51] On June 8, 2017, the FDA requested that Endo withdraw its reformulated Opana ER given the dangerous growth of abuse of that product.[52] The FDA determined that risks of the reformulated Opana ER outweighed the benefits.[53] Endo agreed to the withdrawal.[54]

In 2010, at the height of the opioid epidemic, Endo acquired Qualitest, a major manufacturer, seller, and distributor of generic opioids.[55] Qualitest's biggest opioid product was generic Vicodin (hydrocodone/APAP).[56] Qualitest had been selling opioids since at least 2001.[57] In 2015, Endo acquired Par, another manufacturer of generic opioids.[58] Prior to its acquisition, Par's biggest opioid product was generic Percocet.[59] After the acquisition, Endo consolidated the entirety of its generic opioid operations (including Qualitest) into Par.[60] Endo remained responsible for its branded opioid portfolio.[61] During the entire time Endo, Par, and Qualitest were manufacturing and selling opioids, they failed to maintain effective controls against diversion, which they were legally required to do.[62]

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51 Ex. 121 [ENDO-CHI_LIT-00008100-101 at 101]; Ex. 122 [Walker Dep. Ex. 23 (E0734) at p. 1].

52 Ex. 122 [Walker Dep. Ex. 23 (E0734) at p. 1]; Ex. 120 [Walker Dep. at 464:13 – 465:15, 467:2-5].

53 Ex. 120 [Walker Dep. at 464:17 – 465:3, 474:21 – 475:6, 488:2-16]; Ex. 122 [Walker Dep. Ex. 23 (E0734) at p. 1].

54 Ex. 120 [Walker Dep. at 435:18 – 435:2]. The FDA asked Endo to cease shipping the reformulated Opana ER by August 31, 2017. Ex. 120 [Walker Dep. at 474:18-20]. Despite the FDA finding that the risks of the drug outweighed the benefits, Endo chose not to stop selling it immediately and instead continued to sell it until the end of August 2017. Ex. 120 [Walker Dep. at 465:16-23, 467:2-15, 468:23 – 469:16, 470:19 – 473:18]; Ex. 123]. In fact, in order to sell as much of the drug as possible before that date, Endo offered a 20% discount to its wholesalers. Ex. 124; Ex. 120 [Walker Dep. at 475:20 – 477:24, 479:20-24, 484:2-8, 485:22 – 487:15, 489:2 – 490:21]; Ex. 125. Endo sold over $100 million worth of Opana ER from the date of the FDA's advisory committee meeting in March 2017 through August 2017. Ex. 120 [Walker Dep. at 492:9 – 496:14]; Ex. 126 [Walker Dep. Ex. 28 at E0651.4].

55 Ex. 117 [Campanelli Dep. at 30:21 – 31:4]; Ex. 127 [PAR_OPIOID_MDL_0001593258-275 at 260-261]; Ex. 120 [Walker Dep. at 68:20 – 69:11].

56 Ex. 117 [Campanelli Dep. at 58:15-21, 136:17 – 137:23].

57 Ex. 117 [Campanelli Dep. at 143:22 – 146:20].

58 Ex. 117 [Campanelli Dep. at 31:13-15, 32:4-7].

59 Ex. 128 [Macrides Dep. Ex. 16]; Ex. 117 [Campanelli Dep. at 153:6 – 154:3].

60 Ex. 119 [Macrides Dep. at 82:4-17, 83:12-19]; Ex. 129 [Norton Dep. at 124:11-15]; Ex. 120 [Walker Dep. at 69:6-1481:23 – 82:1]; Ex. 117 [Campanelli Dep. at 32:8-18].

61 Ex. 120 [Walker Dep. at 25:6-14, 69:6-14]; Ex. 119 [Macrides Dep. at 83:12-19].

62 At all relevant times, Par and Qualitest were "registrants" under the CSA. Ex. 117 [Campanelli Dep. at 32:8-18, 34:11 – 35:1, 136:17-23]; Ex. 119 [Macrides Dep. at 167:1-14, 168:2-6]. Although Endo was not technically a registrant, because it outsourced the manufacture and distribution of its opioids, it has conceded that it owed a duty to maintain effective controls against diversion. Ex. 119 [Macrides Dep. at 62:8 – 64:17, 94:5-21]; Ex. 130 [ENDO-OPIOID_MDL-01500831-936 at 834, 850-851, 920]; Ex. 131 [ENDO-CHI_LIT-00234542-587 at 564-565]. It also represented to the

1. Endo failed to maintain effective controls against diversion.

Endo failed to maintain effective controls against diversion because it employed a rigid "excessive orders" system operated by sales and customer service personnel, never looked to available data on its customers' customers, and failed to conduct any meaningful due diligence of its customers. It never determined any order to be suspicious, nor did it report any orders flagged by its SOM program to the DEA.

Until at least mid-2014, Endo's internal order review system was admittedly a "limited" system using a rudimentary algorithm that was designed only to identify "excessive" orders from a commercial perspective, rather than suspicious orders based on unusual volume, frequency, or pattern.[63] Specifically, Endo's "limited SOM Program" looked at its "buying (wholesalers) customers' 3 month and 12 month history and if any order [wa]s above the 3 or 12-month it [went] on hold until it [wa]s reviewed by Customer Service."[64]

Endo's apparent justification for its "[l]imited SOM Program" was that UPS, the DEA registrant Endo used to process and ship orders,[65] had its own SOM program.[66] Yet Endo and Qualitest conducted an audit of UPS's SOM system in 2013 and found that UPS had not reported any Endo/Qualitest product orders as "suspicious orders" to any agency, did not visit customers, lacked the functionality to visit or know customers' customers, and did not utilize chargeback data, trending analyses, or modify its program based on current diversion trends.[67] Regardless, Endo acknowledges

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government, including the DEA, that it would monitor orders and distribution for signs of diversion, including suspicious orders. Ex. 132 [ENDO-OPIOID_MDL-00451334]; Ex. 133 [ENDO-OPIOID_MDL-01706006-011 at 008-009]; Ex. 131 [ENDO-CHI_LIT-00234542-587 at 564-565]; Ex. 134 [PAR_OPIOID_MDL_0001596408-442 at 408-410]; Ex. 119 [Macrides Dep. at 121:4 – 122:3].

63 Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 985]; Ex. 120 [Walker Dep. at 31:7-10, 31:24 – 32:2, 34:4-6, 35:7-11, 73:14 – 75:17]; Ex. 136 [EPI000620553-554 at 553].

64 Ex. 137 [ENDO-OPIOID_MDL-01239749-753 at 749]; Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 985].

65 Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 976]; Ex. 120 [Walker Dep. at 59:10-19].

66 Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 976, 985]; Ex. 137 [ENDO-OPIOID_MDL-01239749-753 at 749].

67 Ex. 138 [Norton Dep. Ex. 14 (PAR_OPIOID_MDL_0000376972-973 & attachment; E0588) at E0588.9]; Ex. 139 [PAR_OPIOID_MDL_0000404285]; Ex. 120 [Walker Dep. at 629:15 – 631:16, 633:18 – 634:13, 636:8 – 638:21]; Ex.

it bears the ultimate responsibility for performing customer due diligence: "The customer relationship, the customer diligence is with Endo in that case. . . . [T]he ultimate responsibility for the customer resides with Endo, not with UPS."[68]

Beginning in May 2014, Endo expanded its algorithm for identifying suspicious orders to include three order characteristics—quantity, size, and frequency—by class of customer trade.[69] Yet it does not appear that Endo ever had any SOM-specific SOPs.[70] Nor did Endo ever utilize chargeback data or IMS/IQVIA data, to which it had access, as part of its internal order review process for its branded opioids.[71] Endo also never conducted due diligence site visits of its customers, despite recognizing the importance of such visits.[72]

At all times, Endo's internal review system was handled by employees in its customer service department.[73] Endo's Director of Distribution and Customer Service, Lisa Walker,[74] testified that in

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140 [PAR_OPIOID_MDL_0000404096-097 at 095]. *See also* Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 983] (2016 summary of UPS SOM program; "The client needs to assist (as needed) with contacting the customer whose order is in a pended status, as UPS SCS does not maintain relationships with our client's customers."); Ex. 141 [UPSSCS0007432-433 at 432] (2009 summary of UPS SOM program; "Because UPS SCS does not hold the relationship directly with the registrants for outbound shipments, it is often not possible for UPS SCS to specifically 'know our customers' as recommended by the [DEA] with regard to SOM. Because of these challenges and UPS SCSs lack of direct contact with our clients' customers, UPS SCS is unable to directly profile the entities to whom Controlled Substances and List I Chemicals are shipped, by conducting routine customer questionnaires, on-site visits, having letters of agreement of product use for legitimate medicinal purposes, etc."); Ex. 120 [Walker Dep. at 96:4-14, 251:10-14].

68 Ex. 119 [Macrides Dep. at 544:14 – 545:14]; *see also* Ex. 142 [ENDO-OPIOID_MDL-05968962-963]. Notably, at one point, Endo asked UPS whether it could carry out the due diligence on Endo's behalf, but UPS made it clear it could not carry out Endo's "know your customer" duties. [ENDO-OPIOID_MDL-0000369517]; *see also* Ex. 141 [UPSSCS0007432-433 at 432]; Ex. 120 [Walker Dep. at 254:13 – 155:3].

69 Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 985]; Ex. 287 [ENDO-OPIOID_MDL-01334119-124]; Ex. 120 [Walker Dep. at 83:17-20]. Purportedly, this "same SOM program" was to be implemented for Qualitest in July 2014. Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 985].

70 Ex. 120 [Walker Dep. at 300:23 – 304:14, 305:19 – 314:2]; Ex. 142 [ENDO-OPIOID_MDL-05948286-292]; Ex. 146 [Walker Dep. Ex. 8 (ENDO-OPIOID_MDL-05950068-072 & attachment; E0674)].

71 Ex. 120 [Walker Dep. at 162:23 – 163:24, 175:6-21, 190:1-5, 635:1-7].

72 Ex. 120 [Walker Dep. at 166:11-12, 168:24 – 169:17, 171:1-21, 173:13-18, 632:24 – 635:7]. Endo's Director of Distribution and Customer Service claimed Endo relied on Qualitest and Par to perform site visits and due diligence, although she admittedly did not know when those site visits began. Ex. 120 [Walker Dep. at 164:9 – 168:22, 631:18 – 632:15, 634:17 – 635:7]. Yet Qualitest's former head of DEA compliance testified that her group had **no responsibility** for Endo's branded business. Ex. 129 [Norton Dep. at 32:6-9, 346:13-18].

73 Ex. 120 [Walker Dep. at 42:24 – 43:18, 53:5 – 54:10]; Ex. 135 [ENDO-OPIOID_MDL-05969976-988 at 977].

74 Ex. 120 [Walker Dep. at 556:3-7].

the twenty years she has been at Endo,[75] she does not recall **any** order being determined to be "suspicious" by her or her team.[76] Nor does she recall UPS ever flagging an order as "suspicious."[77] This is despite the fact that tens of thousands of order line items for controlled substances were flagged under Endo's internal review system.[78] Endo never blocked shipment of any of these flagged orders.[79] Moreover, neither Endo nor UPS ever reported a suspicious order for Endo's products to the DEA.[80]

2. Qualitest failed to maintain effective controls against diversion.

Qualitest failed to maintain effective controls against diversion because, until at least the spring of 2013, it applied SOM review only to "retail" customers, used a rigid formula that did not examine orders for unusual size, frequency, or pattern or account for class of trade, ignored available data on its customers' customers, and failed to conduct any meaningful due diligence. Even after Qualitest revamped its SOM program in late 2013, it lacked real rigor, independence, and consistency.

Both prior to and after its acquisition by Endo, Qualitest's SOM process was severely deficient. In an August 2008 audit, the auditor, a former DEA official,[81] stated that "[t]he Qualitest system for reporting suspicious orders to DEA needs to be improved to comply with 21 CF 1301.74."[82] For example, Qualitest's employees were "not aware that in addition to notifying DEA of sales that were above established thresholds and suspicious, they are expected to report to DEA suspicious orders,

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75 Ex. 120 [Walker Dep. at 56:5-11, 555:24 – 556:4].

76 Ex. 120 [Walker Dep. at 54:12-18, 63:16-22, 65:20 – 66:4, 352:6-8]; *see also* Ex. 119 [Macrides Dep. at 107:1-13] ("We did not have any orders that we deemed suspicious during th[e] time period [from 1999 to 2019].).

77 Ex. 120[Walker Dep. at 66:19 – 66:2, 352:6-8].

78 Ex. 120 [Walker Dep. at 79:13 – 122:8]; Ex. 134 [PAR_OPIOID_MDL_0001596408-442 at 421-442].

79 Ex. 120 [Walker Dep. at 95:16 – 96:2, 106:6-17, 109:4-10]; Ex. 119 [Macrides Dep. at 99:15 – 100:16, 107:1-17].

80 Ex. 120 [Walker Dep. at 55:5-11] ("Q: Has Endo ever reported a suspicious order for one of its branded products to the DEA? A: No, we have not.") (internal objection omitted), 57:12-20, 66:4 – 67:18 ("[N]o, nothing has been – that I recall, nothing has been reported to the DEA."), 107:22-24 ("Q: None were cancelled and no one was reported? A: That's correct."), 118:16-24, 352:6-8, 630:15-23; Ex. 139 [PAR_OPIOID_MDL_0000404285]; Ex. 119 [Macrides Dep. at 95:3 – 99:14, 107:10-19].

81 Ex. 119 [Macrides Dep. at 387:17 – 388:4].

82 Ex. 147[PAR_OPIOID_MDL_0000076009-011 at 010].

even if the sale was declined by Qualitest."[83] Notably, in 2012, there were at least two occasions in which "controlled product [was] released that should not have been."[84]

Even into 2013, Qualitest's SOM program had multiple deficiencies.[85] The program, which had been "built in pieces[,]" "only applie[d] to the retail side of the business[,]" despite Qualitest knowledge that the "DEA requires it to apply to all customers."[86] Orders were flagged only on the basis of "historical purchases by an individual customer (thresholds)," and not by size, pattern, or frequency as required by CSA regulations.[87] The sales department set the threshold amounts and they were authorized to increase them if requested by the customer.[88] A 2009 Qualitest SOM audit review found that Qualitest's employees were simply modifying large orders by dividing them into several smaller orders to ensure each modified order cleared Qualitest's SOM thresholds.[89] In other words, the customer still received the amount of opioids it originally requested, it was merely divided into

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83 Ex. 147 [PAR_OPIOID_MDL_0000076009-011 at 010]. *See also* Ex. 148 [PAR_OPIOID_MDL_0000398174-191 at 177] (2009 audit noted: "Each Order Release that is rejected or modified by QT should be sent to DEA as a suspicious order.").

84 Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.24]; Ex. 129 [Norton Dep. at 387:14 – 388:3].

85 *See, e.g.,* Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.14-16]; Ex. 119 [Macrides Dep. at 428:11 – 429:7].

86 Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.24]; Ex. 129 [Norton Dep. at 288:11-15, 291:3-24, 294:6-14, 386:17 – 387:13, 388:8-18, 389:5-11]; Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.14-15] (noting that other classes of trade were "not evaluated for SOMS").

87 Ex. 152 [PAR_OPIOID_MDL_0000216198-201 at 199]; Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.15] (Qualitest internally acknowledging in 2013 that one of the issues with its current SOM process is that there is "[n]o check for order frequency and pattern discrepancies"); Ex. 153 [PAR_OPIOID_MDL_0000034190-215 at 201, 209] (in 2/13, Qualitest internally recommending that its DEA Compliance Team "[i]mplement system solution that identifies orders based on unusual size, orders deviating substantially from normal pattern and order of unusual frequency[,]" "[c]reate procedures for escalating exceptions[,]" and "[r]evise and implement a new customer addition"; recognizing need to "[i]mplement a robust suspicious order monitoring system that guarantees reliability in the legitimacy of our customer base").

88 Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.14-15]; Ex. 129 [Norton Dep. at 289:19 – 290:6, 297:2-4].

89 Ex. 148 [PAR_OPIOID_MDL_0000398174-191 at 177] ("The review of Order Release Requests showed that many requests were made for quantities of drugs that were several times greater than the current limit set in the order monitoring system. In most of those instances, the size of the order was cut down and the order was approved to be released, with some increase to the limit in the Order Monitoring System.").

multiple orders rather than one large order. Yet, Qualitest never reported the size of the original single order to the DEA as suspicious, as required by CSA regulations.[90] Even Qualitest's former Director of DEA Compliance agreed that working with customers to structure their orders so they stay within the thresholds is "a very bad practice" that "defeats the purpose of the program" and that a company that does that is "not maintaining effective controls against diversion[.]"[91]

Qualitest also shipped orders that fell within its own established threshold even when it knew "that the customer had been limited in quantity for the same drug by another wholesaler."[92] It did not evaluate chargeback data or other third-party data for SOM.[93] Nor did it conduct rigorous due diligence of its customers or its customers' customers.[94] Any site visits or due diligence was carried out by Qualitest's sales personnel, rather than compliance staff,[95] which was viewed as a "conflict of

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90 Ex. 148 [PAR_OPIOID_MDL_0000398174-191 at 177] ("Although the original order requested a quantity of controlled substances that was larger than QT was willing to ship to the customer, no report of a suspicious order was sent to the DEA as required by 21 CFR 1301.74(b).").

91 Ex. 129 [Norton Dep. at 356:15 – 358:5].

92 Ex. 147 [PAR_OPIOID_MDL_0000076009-011 at 011].

93 Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.24] (noting in 2013 that its SOM system "needs to be revamped, all customers added, IMS data and chargeback data incorporated . . ."); Ex. 129 [Norton Dep. at 258:4-18, 305:2-15, 307:4 – 308:4, 319:20 – 320:15, 342:14-17, 372:13 – 374:15, 388:20-22, 389:5-11]; Ex. 153 [PAR_OPIOID_MDL_0000034190-215 at 209] (2/13 internal Qualitest presentation recommending that Qualitest start "[u]tiliz[ing] chargeback and IMS data to 'know your customer's customer' " in the first quarter of 2014); Ex. 152 [PAR_OPIOID_MDL_0000216198-201 at 199]; Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.16]; Ex. 138 [Norton Dep. Ex. 14 (PAR_OPIOID_MDL_0000376972-973 & attachment; E0588) at E0588.7].

94 Ex. 147 [PAR_OPIOID_MDL_0000076009-011 at 011] (8/08 DEA audit report stated: "Generally speaking, Jeremy Tatum is responsible for releasing orders for retail pharmacies and doctors where the quantity shipped is above the established thresholds for the particular drug as established by Qualitest. At the present time, the only information that Mr. Tatum has to consider when make the decision is the customer history, possible a note or email from the account representative, or input from the phone sales representative. It is imperative that the Controlled Substance Questionnaire that has been developed be finalized and put into the system. **Without that level of information, Qualitest will be making the ship/not ship decision with insufficient information**.") (emphasis added); Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.29] (as of 2013, Qualitest checked customers once a year to "assure they have a valid DEA registration[,]" despite the "DEA requir[ing] [it] verify that a customer has a valid DEA registration prior to shipment of any controlled product"; "We need to check registrations more frequently to limit risk."); Ex. 152 [PAR_OPIOID_MDL_0000216198-201 at 199-201]; Ex. 154 [PAR_OPIOID_MDL_0000390035-037 at 037] (discussing 2011 DEA inspection: "DEA then spoke about SOMS at length and also discussed the need to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits. This is not something we are currently doing and another item we will need to work on improving."); Ex. 129 [Norton Dep. at 253:6-18, 326:4-8, 344:11 – 345:17, 400:9-21].

95 Ex. 152 [PAR_OPIOID_MDL_0000216198-201 at 200] ("Ms. Hernandez stated the only individuals who visit their customers are from the sales force and not compliance."); Ex. 153 [PAR_OPIOID_MDL_0000034190-215 at 209]

interest" by the DEA.[96] Qualitest lacked sufficient SOM-related SOPs until late 2013.[97] Moreover, "[n]o mandatory, routine DEA training exist[ed] for employees handling controlled substances" and "[k]nowledge of DEA regulations [wa]s not incorporated in employee's job descriptions or performance reviews."[98] This is particularly egregious considering that approximately 70% of Qualitest's business was controlled substances.[99]

Qualitest recognized that failures in its SOM program could lead to diversion of opioids with "heart-wrenching consequences."[100] Yet Qualitest itself internally admitted that its SOM program was "[i]nadequate[.]"[101] It further acknowledged that its SOM program needed to be revamped to address these deficiencies and that the risks associated with its current program were severe.[102] The DEA agreed. At a March 2013 meeting with Qualitest, the DEA Staff Coordinator stated that "Qualitests' [sic] current [SOM] system as explained to him and as seen on their ARCOS data is **inadequate to**

(2/13 internal Qualitest presentation recommending that Qualitest start "utilizing [an] external audit team" to "[i]mplement on-site customer audits" in the first quarter of 2014); Ex. 129 [Norton Dep. at 81:7-24]. Indeed, it does not appear that Qualitest even had a DEA compliance department prior to 2013. Ex. 155 [ABDCMDL00337067-073 at 068] (noting it had sent a letter to its customers in late 2013 "explaining [its] development of a DEA Compliance Dept. and our SOMS program . . ."); Ex. 129 [Norton Dep. at 340:10-14] (Qualitest had no manager of the SOM program prior to 9/13).

96 Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.15] ("Retail Pharmacy review and approval is handled by the Sales department. Sales department should not set the threshold amount or be involved with releasing held orders. DEA views this as a conflict of interest and consider the sales department as a department that is driven by dollars."; "No separate/unbiased check of order quantity out side [sic] of Sales and Marketing departments."); Ex. 129 [Norton Dep. at 319:2-18].

97 Ex. 156 [PAR_OPIOID_MDL_0000002282-309]; Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.28] ("SOPs need to be created for several activities related to DEA compliance but more importantly, departmental SOPs need to be evaluated and be made to incorporate DEA compliance requirements into them. This is a lengthy task based on the number of SOPs that are needed and the company's lack of a robust, automated change control process."); Ex. 129 [Norton Dep. at 341:7-8].

98 Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.28]; Ex. 129 [Norton Dep. at 391:3-24].

99 Ex. 129 [Norton Dep. at 391:9-12].

100 Ex. 155 [ABDCMDL00337067-073 at 069]; *see also* Ex. 129 [Norton Dep. at 271:4 – 287:7]; Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.1-6].

101 Ex. 153 [PAR_OPIOID_MDL_0000034190-215 at 197]; Ex. 129 [Norton Dep. at 378:12 – 380:9, 389:15-19].

102 Ex. 151 [Norton Dep. Ex. 17 (PAR_OPIOID_MDL_0000363469-473 & attachments; E0574) at E0574.24]; Ex. 129 [Norton Dep. at 389:21 – 390:25].

say the least[.]"[103] This was further confirmed by external consultants who reviewed Qualitest's SOM program in January 2013: "The consultants concluded that our 'current SOM program, systems and procedures *do not meet the regulatory requirements*[.]' "[104]

Qualitest's purported improvements to its SOM program in late 2013 were nothing more than window dressing. Although Qualitest claimed it would now require confirmation that its customers had SOM practices in place to ensure legitimate use of its products, in actuality, even when its customers' SOM policies were lacking or raised concerns, Qualitest continued to seek ways to work with those customers rather than terminating the relationship.[105] Indeed, Qualitest never reported or ceased distribution for any of its biggest customers or those customers' customers.[106] It was only when Qualitest began looking at chargeback data that it found and reported problematic secondary customers.[107] Even the due diligence process Qualitest implemented in late 2013 was not applied conscientiously or consistently. For example, orders from large "Tier 1" customers[108] could not be reported or stopped as suspicious through the process that applied to other customers, but were instead routed to the Chief Operating Officer ("COO").[109] Similarly, only the COO had the authority to terminate Qualitest's relationship with a Tier 1 customer, whereas the SOM team had the authority to discontinue shipments of controlled substances to Tier 2 & Tier 3 customers.[110]

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103 Ex. 152 [PAR_OPIOID_MDL_0000216198-201 at 201] (emphasis added); *see also* Ex. 129 [Norton Dep. at 259:12 – 260:4].

104 Ex. 157 [Norton Dep. Ex. 15 (PAR_OPIOID_MDL_0000034190, 0001424664-667 & attachment; E1052) at E1052.2-4, 7-12] (emphasis added); *see also* Ex. 129 [Norton Dep. at 360:14-22, 382:13-22].

105 Ex. 158 [ENDO-HSGAC_0010594-595 at 594]; [PAR_OPIOID_MDL_0000020898].

106 Ex. 160 [Par's 3/4/19 Suppl. Resp. to Ps Rogs at response to ROG 32].

107 Ex. 129 [Norton Dep. at 450:4 – 453:16]; [PAR_OPIOID_MDL_0000020898]; [ENDO-HSGAC_0010368]; Ex. 160 [PAR_OPIOID_MDL_0000021256-272 at 268-27]; Ex. 160 [Par's 3/4/19 Suppl. Resp. to Ps Rogs at pp. 62-63].

108 "Tier 1" customers were customers with a minimum of ten million dollars in overall sales and/or 750,000 dosage units of controlled substances or List 1 chemical purchases annually. Ex. 163 [PAR_OPIOID_MDL_0001642692-695 at 693].

109 Ex. 163 [PAR_OPIOID_MDL_0001642692-695 at 694]; *see also* Ex. 147 [PAR_OPIOID_MDL_0000076009-011 at 010] (8/08 DEA audit noted that Qualitest's SOP for Suspicious Orders "states that Qualitest Senior Management will make a determination if a suspicious order is reported to DEA").

110 Ex. 163 [PAR_OPIOID_MDL_0001642692-695 at 693, 695].

Given the severe deficiencies in its SOM program, it is not surprising that Qualitest has been the subject of several DEA investigations, letters of admonition, civil penalties, and enforcement actions.[111] Among other things, the DEA found Qualitest records could not account for, and had deviations of, at least 9 million pills for the period of December 31, 2012 through July 14, 2014.[112]

3. Par failed to maintain effective controls against diversion.

Par failed to maintain effective controls against diversion because it had no effective, independent SOM program prior to 2015 and, thereafter, operated under the deficient program Qualitest used.

Par was selling generic opioids prior to 2010, yet an outside audit dated May 8, 2010 determined that Par had *no SOM program whatsoever* at that time.[113] Par's first SOM SOP was not implemented until April 2012.[114] The 2012 SOP failed to define what a "suspicious order" was or explain when and how to report suspicious orders to the DEA.[115] It simply stated: "Weekly replenishment Purchase Orders are analyzed by Account Service Executives verses Customer provided usages. If quantities are higher than the average transmission it is question. The Buyer is contacted to review, a written request is asked as to the reason for the increase. It is reviewed to ensure it is correct and warranted."[116] In October 2012, the SOM SOP was modified to add a section on "Reporting Suspicious Criminal Activities": "If criminal activity is suspected, report the following to the state agencies that licensed the facility (e.g. board of pharmacy) and Food and Drug

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111 Ex. 129 [Norton Dep. at 84:2 – 90:4]; Ex. 164 & Ex. 168 [PAR_OPIOID_MDL_0001059825-827]; Ex. 165 [PAR_OPIOID_MDL_0000399716 at 2]; Ex. 166 [PAR_OPIOID_MDL_0001615738 at 3]; Ex. 167 [PAR_OPIOID_MDL_0002102288 at 4].

112 Ex. 164 & Ex. 168 [PAR_OPIOID_MDL_0001059825-827]; Ex. 129 [Norton Dep. at 87:21 – 88:7].

113 Ex. 169 [PAR_OPIOID_MDL_0001053153-168 at 162] ("There is no Suspicious Order Monitoring program in place."); *see also* Ex. 119 [Macrides Dep. at 164:9 – 166:16, 174:17 – 175:1, 181:6-17, 182:18-24].

114 Ex. 119 [Macrides Dep. at 177:18 – 180:17, 183:1 – 186:13, 186:19 – 187:2]; Ex. 170 [PAR_OPIOID_MDL_0001058273-279 at 274-277].

115 Ex. 119 [Macrides Dep. at 187:4 – 189:16]; Ex. 170 [PAR_OPIOID_MDL_0001058273-279 at 274-277].

116 Ex. 170 [PAR_OPIOID_MDL_0001058273-279 at 275]; Ex. 119 [Macrides Dep. at 187:22 – 190:12].

Administration (FDA), as well as Drug Enforcement Administration (DEA) for controlled substances within three days of suspecting criminal activity."[117]

Even in 2015, when it was acquired by Endo, Par's order review process was severely deficient.[118] An outside audit of Par's SOM process conducted that year determined that "Par's current SOM system as it currently operates may be difficult to explain and defend during a DEA review."[119] At that time, there were no SOMS employees and the SOMS function was limited to a manual review by sales or customer service personnel,[120] rather than regulatory employees, which was "viewed as a conflict of interest by the DEA."[121] Par conducted no customer due diligence other than confirming the customer held a DEA license.[122] There was no reliable review for unusual size, pattern, or frequency.[123] Moreover, Par's SOP required only that "criminal" activities be reported to the DEA, rather than suspicious orders.[124] Par's outside auditor warned Par that this requirement "should be

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117 Ex. 173 [PAR_OPIOID_MDL_0001410508-513 at 510].

118 Ex. 171 [PAR_OPIOID_MDL_0001024034-079]; Ex. 172 [PAR_OPIOID_MDL_0001596366-369 at 367].

119 Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 057, 073].

120 Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 073-074] (6/15 audit notes that under Par's SOM SOP: "'Sales Operations' is responsible for ensuring that Par Pharm is 'in line' with DEA requirements. . . . If customers order more than would be expected, a sales person would interview the customer to determine whether there is a legitimate reason for the order."; auditor recommends that "SOM decisions should be managed by regulatory officials rather than sales officials or customer service account representatives" and that "[a]ny employees that receive incentives for controlled substance orders should not be involved in evaluating either accounts or orders"); Ex. 170 [PAR_OPIOID_MDL_0001058273-279 at 274]; Ex. 173 [PAR_OPIOID_MDL_0001410508-513 at 508]; Ex. 119 [Macrides Dep. at 191:10 – 192:12].

121 Ex. 150 [Norton Dep. Ex. 12 (PAR_OPIOID_MDL_0000018920-18936 & attachments; E0606) at E0606.15]; Ex. 172 [PAR_OPIOID_MDL_0001596366-369 at 367]. After Par's acquisition by Endo, the former elements of the Qualitest DEA compliance unit took responsibly for SOMS for both businesses. Ex. 172 [PAR_OPIOID_MDL_0001596366-369 at 366-367].

122 Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 073] (6/15 audit notes that under Par's SOM SOP: "Due diligence is conducted on new accounts at the time they become new and quarterly. Due diligence consists of assuring that the customers have a DEA registration."; auditor recommended that Par "conduct additional 'due diligence' on all customers" and that "to enhance due diligence site reviews are strongly recommended").

123 Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 073] (6/15 audit of Par's SOM SOP states: "There is no indication that [Par's SOM] system measures or attempts to measure order size, pattern and frequency. These are the requirements in the regulations.").

124 Ex. 173 [PAR_OPIOID_MDL_0001410508-513 at 510]; Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 056, 073] (4/15 audit report notes: "[Par's] SOP does not contain instructions for reporting suspicious orders. Instead there is a section, which is 'bolded' which states that 'Criminal Activities' will be reported to federal and state agencies . . ."); Ex. 119 [Macrides Dep. at 196:6 – 197:18].

corrected as soon as possible, since it misses the point of the regulations[,]" which is that "[s]uspicious orders should be reported as soon as they are identified."[125]

Par did not identify or report any suspicious orders from 2010 through 2012.[126] Between 2013 and 2017, a multitude of orders were flagged by its SOM system, but they were all cleared to ship.[127] There is no indication Par reported any suspicious orders to the DEA prior to 2015.[128]

E. J&J Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

The pharmaceutical products of Janssen Pharmaceuticals, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc. are distributed by Johnson Ortho McNeil Pharmaceutical's Customer Service and Distribution Center ("JOM," and collectively with Janssen Pharmaceuticals, Inc., "Janssen"[129]).[130] Janssen's opioid portfolio includes and/or included Duragesic (fentanyl patch) and Nucynta/Nucynta ER (tapentadol hydrochloride, immediate and extended release).[131] Duragesic was launched in the 1990s.[132] Nucynta and Nucynta ER launched in June 2009 and June 2011, respectively.[133] Janssen sold the rights to Nucynta and Nucynta ER in early 2015.[134]

Janssen's SOM program began in 2005 when it implemented its first SOM SOP.[135] Since 2005,

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125 Ex. 171 [PAR_OPIOID_MDL_0001024034-079 at 074].

126 Ex. 119 [Macrides Dep. at 190:13-22].

127 Ex. 134 [PAR_OPIOID_MDL_0001596408-442 at 414].

128 Ex. 119 [Macrides Dep. at 530:6 – 532:14]; [Macrides Dep. Ex. 41] (listing eight suspicious orders reported between 1/15 and 4/17).

129 "Janssen" also includes Noramco, Inc., a wholly-owned subsidiary of Johnson & Johnson, which produced the active ingredients for Janssen's pharmaceutical products. Ex. 174 [Dempsey Dep. Vol. I at 17:12-18, 34:1-12, 37:7 – 39:23] [*not sure whether we care about including Noramco or not – I didn't see them mentioned in the documents with respect to the SOMS program, and if we include them J&J will likely respond that we improperly grouped all the J&J defendants in our MSJ as "Janssen" and that we provided no evidence for Noramco*]

130 Ex. 175 [Dempsey Dep. Ex. 5 (JAN-MS-03054480-482) at p. 1 of the ppt.].

131 Ex. 176 [JAN-MS-04199587 at slide 12]; Ex. 177 [JAN-MS-00653403 at slides 1, 4].

132 Ex. 177 [JAN-MS-00653403 at slide 4].

133 Ex. 176 [JAN-MS-04199587 at slide 12].

134 Ex. 179 [JAN-MS-02983598-599 at 599].

135 Ex. 180 [JAN-MS-03741170-176]; Ex. 181 [JAN-MS-03741177-200]; Ex. 182 [JAN-MS-03741201-205]. Janssen revised its SOM SOP in 2013. Ex. 183 [JAN-MS-03124101-110].

Janssen's SOM program has used the same algorithm and same definition for a suspicious order: "A potentially suspicious or excessive controlled substance order can be defined as an order that exceeds the minimum order quantity requirements, and is above 3xs (300%) of the calculated, 12 month, per weekly order average."[136] Janssen was well aware that the CSA defines "suspicious orders" to include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.[137] Yet, Janssen's SOM program *only* monitored for orders of unusual size for customers with a prior order history;[138] it failed to ever monitor for frequency and/or pattern in real time.[139] Accordingly, as Janssen has conceded, its SOM program would not detect: (i) multiple customer orders during a given month; (ii) orders which consisted of gradual quantity increases of a controlled substance over time; and (iii) a new customer's orders for controlled substances which initially commence with larger than normal quantities and remain at a constant.[140]

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136 Ex. 183 [JAN-MS-03124101-110 at 101]; *see also* Ex. 180 [JAN-MS-03741170-176 at 172] (2005 SOP did not define "suspicious order" but stated that an order should be flagged if it had "a % variance value greater than 3x the customer's average order over a 52-week period"); Ex. 184 [JAN-MS-00454956-958 at 957-958]; Ex. 185 [JAN-MS-02987651-656 at 652]; Ex. 186 [Dempsey Dep. Vol. II at 445:9 – 446:1, 471:23 – 472:18, 481:22 – 482:13, 559:22 – 566:2].

137 Ex. 186 [Dempsey Dep. Vol. II at 434:13 – 435:19, 447:2 – 451:7]; Ex. 187 [JAN-MS-02960654-719 at 712]; Ex. 174 [Dempsey Dep. Vol. I at 51:1-11]; Ex. 186 [Dempsey Dep. Vol. II at 434:13 – 435:19].

138 Ex. 180 [JAN-MS-03741170-176 at 172]; Ex. 183 [JAN-MS-03124101-110 at 101]; Ex. 186 [Dempsey Dep. Vol. II at 472:12 – 473:23].

139 Ex. 188 [JAN-MS-02983578-579 at 578] (on 1/23/18, Janssen's Director of Controlled Substance Compliance acknowledged that the algorithm "only measures quantity and does not consider frequency or pattern of ordering by the same customer"); Ex. 184 [JAN-MS-05444730-737 at 730] ("The DEA guidelines include an expectation for us to flag: • Orders of unusual size[;] • Orders deviating substantially from normal pattern[;] • Orders of unusual frequency[.] We currently have a process to flag unusual based on list 1 chemicals and is not up to current industry practice. The other two requirements are vulnerabilities that must be addressed. Our current monitoring program flags orders of unusual size (a running average of past orders is taken and we flag any order that is 300% more than average). We do not currently account for ordering frequency or cumulative effect of multiple orders in one month against a threshold[.]"); Ex. 186 [Dempsey Dep. Vol. II at 472:19 – 473:18] ("Q:…. I said this algorithm only measures quantity and does not consider frequency or a pattern of ordering by the same customer. Do you agree with that? A: That is what the algorithm does, the quantity. Q: And so you agree with that, right? Yes? A: Yes.").

140 Ex. 185 [JAN-MS-02987651-656 at 652] ("The report rolling average will not show slow increases in order patterns or if a new customer starts at higher levels vs similar size customers."; "The report does not take into consideration multiple orders in one month – the accumulating effect exceeding the total for the month. It compares the one order against the historical 3x12 month week average."); Ex. 188 [JAN-MS-02983578-579 at 578] ("The algorithm compares a customer's order quantity against only that customer's average annual purchases. The algorithm would not detect multiple customer orders during a given week; it would not detect orders which consist of gradual quantity increases of a controlled substance over time; it would not detect a new customer's orders for controlled substances against similar size and geographically-placed customers, and perform national, regional, state and perhaps three-digit zip code comparisons among like size customers."); Ex. 186 [Dempsey Dep. Vol. II at 473:19 – 475:9, 478:6-15, 811:24 – 813:7].

Janssen has previously argued that, after 2012, its SOM program included monthly or quarterly reviews that allowed it to compare the number of controlled and non-controlled products a customer purchased, as well review the customer's complete order history and patterns.[141] However, Janssen's Director of Controlled Substance Compliance, Michele Dempsey, conceded that *only* an order flagged for unusual *size* by the SOM program's one-dimensional algorithm could be stopped for review in real time.[142] Thus, even if Janssen was able to later identify an unusual pattern or frequency in its monthly/quarterly reviews, by that time any order not previously flagged by the algorithm for unusual size would have already been released to the customer.[143] And, as Ms. Dempsey admitted, Janssen did not "want to question release decisions after the fact."[144]

Janssen's SOM program was also materially deficient in other ways. Significantly, it was narrowly designed such that a Schedule II order would only be compared to previous orders of products with **a***n identical SKU* (*i.e.*, the same product at the same strength) placed in the prior 52 weeks.[145] In other words, if a customer ordered 1000 Nucynta 100 mg tablets, the SOM system would only compare that order to the customer's other orders of Nucynta 100 mg tablets placed within the past year. The system failed to take into consideration prior orders from the same customer of Nucynta 50 mg tablets, for example, or of Nucynta ER tablets.[146] Janssen has conceded that its SOM

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141 Ex. 174 [Dempsey Dep. Vol. I at 148:7 – 149:22]; Ex. 186 [Dempsey Dep. Vol. II at 537:19 – 538:4, 806:21 – 807:6].

142 Ex. 174 [Dempsey Dep. Vol. I at 453:8 – 455:13] ("Q: Okay. So the fact that you have a program that has the capability to analyze orders beyond the algorithm only comes into play when that – on that date the order is placed when an order is flagged; isn't that right? A: When the order is flagged as atypical, it gets investigated. And then that includes running all of the historical – looking through the ordering pattern, as well as the frequency part of that. Q: But you can't do an investigation until the order is flagged, right, in realtime? A: Agreed.") (internal objection omitted), 512:20 – 513:5 ("Q: Okay. But an order in realtime in a moment of the day is not investigated, as you testified earlier, until it's first flagged, right? A: Yes. Q:") (internal objection omitted), 803:19 – 804:9 (Dempsey admits Janssen used the one-dimensional algorithm the entire time Nucynta was sold).

143 Ex. 186 [Dempsey Dep. Vol. II at 748:23 – 749:22].

144 Ex. 190 [JAN-MS-05444781-782 at 782]; Ex. 186 [Dempsey Dep. Vol. II at 498:8 – 499:20].

145 Ex. 185 [JAN-MS-02987651-656 at 652]; Ex. 174 [Dempsey Dep. Vol. I at 144:22 – 148:10, 149:23 – 150:15].

146 Ex. 185 [JAN-MS-02987651-656 at 652]; Ex. 174 [Dempsey Dep. Vol. I at 149:23 – 150:15].

system was not designed to aggregate all products, track consolidated customer orders, or compare customers' ordering patterns to those of other like-size customers:

> Current BW report (algorithm) measures orders by NDC number (SKU) not drug class (total fentanyl for example) or consolidated customer (just ship to address). [sic] and does not track total gram base of controlled substances to the consolidated or individual registrant. For example, we do not follow how much methylphenidate (Concerta) is shipped to all HD Smith locations or to the individual locations. We track how much of each SKU is shipped to a location. The team aligned that in the future, our software should track by drug code (in grams base not EA) and consolidate customer locations.
>
> ***
>
> The current report does not compare customers against similar wholesalers and their ordering patters [sic]. The team aligned that in the future, our software should differentiate by customer type (large, medium, small wholesaler).[147]

Significantly, Janssen had access to transactional sales data that could have allowed it to identify suspicious orders based on unusual size, pattern, *and* frequency (as required under the CSA), including, but not limited to, chargeback data,[148] wholesalers' inventory and sales data,[149] and third-party data from Integrichain and ValueTrak.[150] Among other things, this data allowed Janssen to track the purchasing behavior of its customers and its customers' customers, down to the retail level (*e.g.*, individual pharmacy locations), as well as the prescribing behavior of individual physicians.[151]

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147 Ex. 185 [JAN-MS-02987651-656 at 652-653] (notes from Janssen's 12/13/17 SOM Workshop). *See also* Ex. __ Ex. 188 [JAN-MS-02983578-579 at 578] (1/23/18 e-mail from Janssen's Director of Controlled Substance Compliance suggesting future modifications to the SOM program to address these deficiencies); Ex. 189 [JAN-MS-05444730-737 at 736] (in mid-2018, Janssen proposed enhancing its SOM program so that it would "compl[y] with applicable state and DEA regulations"); Ex. 174 [Dempsey Dep. Vol. I at 365:24 – 366:13].

148 Janssen had access to chargeback data since 2005. Ex. 191 [JAN-MS-01117436 at slide 3]; Ex. 185 [JAN-MS-02987651-656 at 654].

149 Since at least 2011, Janssen had access to 852 data (wholesalers' inventory and total sales out to their customers) and unblinded 867 data (wholesalers' total sales out to their customers broken out by outlet, *i.e.*, Retail Pharmacies, Hospitals, Long Term Care, Clinics, etc. Last Points-of-Care in the Supply Chain where product is shipped prior to delivering to the patients)). Ex. 191 [JAN-MS-01117436 at slides 3-4]. *See also* Ex. 184 [JAN-MS-00454956-958 at 956]; Ex. 174 [Dempsey Dep. Vol. I at 98:4 – 99:2].

150 Ex. 184 [JAN-MS-00454956-958 at 956]; Ex. 191 [JAN-MS-01117436 at slides 11-12]; Ex. 185 [JAN-MS-02987651-656 at 654].

151 Ex. 184 [JAN-MS-00454956-958 at 956]; Ex. 191[JAN-MS-01117436 at slides 3-6, 10].

Janssen's sales and marketing teams, along with its trade group, extensively utilized this data to promote sales and target high-volume prescribers.[152] Janssen could have used this same data to monitor suspicious prescribers; it chose not to.[153] In fact, Janssen failed to incorporate any of this sales data into its real-time SOM system.[154]

Janssen knew how valuable this data could be when monitoring for suspicious orders. In March 2012, Purdue's Jack Crowley, a former DEA employee,[155] presented a benchmarking seminar to Janssen's executives, including Ms. Dempsey.[156] Mr. Crowley advised Janssen that Purdue had

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152 Ex. 191 [JAN-MS-01117436 at slides 5-6, 10-14, 25] ("New un-blinded data allowed Janssen to gain a number of new insights. . . . Based on purchasing behavior, we can now identify the most valuable individual pharmacies in the marketplace."; "Insights around purchasing behavior of individual outlets can resolve demand issues and help build demand strategies."; "Utilizing 867 data, we were able to create 4 levels of stocking penetration reports for Nucynta ER."); Ex. 184 [JAN-MS-00454956-958 at 956] (using ValueTrak data to identify "hot spot markets prescribers writing the higher strengths" so that such information can be provided to the "JOM Planners and Wholesaler Buyers"); Ex. 174 [Dempsey Dep. Vol. I at 134:18 – 138:23].

153 Ex. 174 [Dempsey Dep. Vol. I at 187:12 – 188:3, 193:22 – 194:8].

154 Ex. 174 [Dempsey Dep. Vol. I at 98:4: - 98:16] (Janssen's Director of Controlled Substance Compliance, Michele Dempsey, was not aware that Janssen "had the ability to unblind and unblock the sales it was making to wholesalers to obtain visibility of [its] inventory at individual retail stores" until 2017), 106:3-8 ("Q: Okay. And yet in 2012, your compliance group wasn't getting this unblended data to see where your drugs were winding up at the retail level, were you? A: No."), 111:3-18 (in 2012, Janssen had access to pharmacy-level stocking tool data; "Q: Yet, you in your compliance group wasn't [sic] getting this stocking tool data while you were looking at suspicious order monitoring in 2012, were you? A: No, we were not."), 132:18 – 134:23 (conceding that the ValueTrak data was not a data source built into Janssen's suspicious order monitoring program), 187:19 – 188:3, 200:14 – 201:5; Ex. 188 [JAN-MS-02983578-579 at 579] (in January 2018, Dempsey, suggested as a **future** modifications to the SOM program that Janssen "[u]tilize IntegriChain data, data from Value Centric's Value Trak 852 and 867 EDI programs to evaluate and/or verify customer inventory levels and activities[,]" and "[e]valuate chargeback data and information in J&J's possession, and determine if any of the data or information is of value to the goals and objectives of the JOM SOM program[,]" and "[c]onsider using chargeback data to assist in evaluating regional distribution trends for J&J controlled substance products"); Ex. 185 [JAN-MS-02987651-656 at 654-655] (during an internal SOM Workshop on December 13, 2017, Janssen suggested that it should "[i]dentify how chargeback/EDI Value Centric data could be routinely used to identify potential suspicious trends at the pharmacy/patient level" and that it "need[ed] to discuss how we can use 852, 867 and Intrachain [sic] data for follow up investigations on atypical orders as well"); Ex. 192 [JAN-MS-02963719-721] (analyzing data on its controlled substance sales to a particular Walgreens only after DEA suspended that Walgreens' license; Dempsey noted: "[W]e should be doing this not just when DEA shuts down Walgreens… Mike and I fear that JOM is going to reduce headcount and there will not be anyone left to do this kind of analysis. These are the key products we should be constantly monitoring but the current process of collecting data is time consuming—took Greg all week."); Ex. 193 [JAN-MS-05444748-763 at 759-760]. As of 2012, Janssen's SOM program required a JOM Customer Service member to run a ValueTrak report only on orders that had already been flagged as suspicious by the program, and even then only to show the customer's inventory and compare that inventory to the demand of the increase. Ex. 183 [JAN-MS-03124101-110 at 105]; Ex. 184 [JAN-MS-00454956-958 at 958].

155 Ex. 194 [Dempsey Dep. Ex. 6; JAN-MS-03115781-783, 03115790-798 at 781]; Ex. 174 [Dempsey Dep. Vol. I at 165:9 – 166:2].

156 Ex. 194 [Dempsey Dep. Ex. 6; JAN-MS-03115781-783, 03115790-798]; Ex. 174 [Dempsey Dep. Vol. I at 163:16 – 164:3, 175:12 – 176:11].

invested heavily in resources to revamp its SOM program in 2008.[157] In particular, Purdue incorporated real-time data feeds from ValueTrak and Integrichain into its SOM system, enabling Purdue to "know [its] customers' customer."[158] Janssen ignored Mr. Crowley's recommendations and made no effort to get to know its customers' customers.[159] Notably, despite attending this benchmarking seminar, and taking nine pages of notes,[160] Ms. Dempsey now claims that she was unaware that other opioid manufacturers were using this type of data prior to 2017.[161] Mr. Crowley reached out to Janssen again in 2013, after he left Purdue, to pitch a program to train Janssen's sales representatives to spot suspicious prescribers.[162] Janssen ultimately chose not to implement that program.[163]

Another significant flaw in the design of Janssen's SOM program was that the algorithm stopped automatically flagging suspicious orders at 3:45 p.m. every day.[164] But orders could be placed

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157 Ex. 194 [Dempsey Dep. Ex. 6; JAN-MS-03115781-783, 03115790-798 at 782].

158 Ex. 194 [Dempsey Dep. Ex. 6; JAN-MS-03115781-783, 03115790-798 at 790-798]; Ex. 174 [Dempsey Dep. Vol. I at 173:17-23, 174:12-17, 176:12 – 177:9, 185:10 – 187:17, 193:2 – 195:1, 196:10 – 200:23]; Ex. 186 [Dempsey Dep. Vol. II at 553:6 – 554:9].

159 Ex. 174 [Dempsey Dep. Vol. I at 173:17 – 174:11, 178:10-23, 179:24 – 180:8, 187:8 – 188:3] ("A: I am – what he was saying at a high level, that Purdue does use prescriber data and analyze where it's coming from. Q: In other words, they were looking at prescriber data as a potential red flag, right? A: It appears that they were for their products. Q: And Janssen and JOM were not doing that, correct? A: No, for our Duragesic and Nucynta and other scheduled products, we did not do trend analysis on the prescriber data as I previously said. We stopped at the wholesaler.") (internal objections omitted), 193:22 – 194:8, 200:14 – 201:5 ("Q: But [Purdue] fed ValueTrak data into their system. Do you see that? A: Yes. Q: Okay. JOM and Janssen did not do that between your meeting, benchmarking meeting on March 21, 2012, and at least January of 2018; is that right? A: No, we did not.").

160 Ex. 194 [Dempsey Dep. Ex. 6; JAN-MS-03115781-783, 03115790-798]; Ex. 174 [Dempsey Dep. Vol. I at 172:20 – 173:7].

161 Ex. 174 [Dempsey Dep. Vol. I at 61:8-22]. Ms. Dempsey also claims she was unaware that Janssen's sales department was using this data. Ex. 174 [Dempsey Dep. Vol. I at 188:5 – 189:2, 190:4 – 191:12]. Incredibly, when asked if this was information she would have wanted to have, she said "No." Ex. 174 [Dempsey Dep. Vol. I at 189:4-9].

162 Ex. 196 & Ex. 197 [Dempsey Dep. Ex. 36; JAN-MS-02984629-631 & attachment] ("We discussed training for the sales force, how to recognize what is suspicious or a cause for concern . . . This is really a white board type exercise, suitable for your small, dedicated sales team (contract sales organization) working within about 10,000 HCP's in the pain management space."); Ex. 186 [Dempsey Dep. Vol. II at 554:14 – 556:21, 557:12 – 558:8].

163 Ex. 186 [Dempsey Dep. Vol. II at 556:22 – 557:11, 558:10 – 558:8].

164 Ex. 185 [JAN-MS-02987651-656 at 652]; Ex. 188 [JAN-MS-02983578-579 at 578]; Ex. 186 [Dempsey Dep. Vol. II at 467:20 – 468:15].

at any time.[165] Accordingly, any Schedule II order placed after 3:45 p.m. would have to be manually checked by someone the next morning, before the order was shipped out, in order to determine whether it was of unusual size.[166] Janssen internally recognized that "there is the potential that an order can be released the next morning without being monitored in the program."[167]

Incredibly, despite the many deficiencies in its SOM program, Janssen did not perform a SOM-related workshop, or use an outside consultant to analyze and improve its SOM program until around December 2017.[168] Both its internal workshop and its outside consultant's report acknowledged the existence of these deficiencies and recommended significant modifications to its SOM program.[169] Of course, by this point in time, Janssen had long since stopped selling Nucynta.[170] Regardless, Janssen has yet to implement many of the recommended modifications.[171]

Janssen not only failed to implement a SOM system that identified all suspicious orders, it failed to report the orders that were actually flagged by its system.[172] In January 2018, Janssen's outside consultant concluded: "It appears that the JOM SOM has not reported an order for controlled substances as suspicious during its time in operation[.]"[173] Janssen claims that this is because "[t]here

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165 Ex. 193 [JAN-MS-05444748-763 at 750]; Ex. 185 [JAN-MS-02987651-656 at 652].

166 Ex. 188 [JAN-MS-02983578-579 at 578]; Ex. 193 [JAN-MS-05444748-763 at 750-751]; Ex. 186 [Dempsey Dep. Vol. II at 457:22 – 459:16].

167 Ex. 185 [JAN-MS-02987651-656 at 652] ("Any time we need to have a review done each morning by personnel leads to potential of error."); Ex. 188 [JAN-MS-02983578-579 at 578] ("Any orders that are received by J&J customer service via EDI after that time may be shipped to a customer the following day without being subjected to the SOM algorithm unless the EDI orders are checked the next morning to ensure the SOM algorithm has been applied."); Ex. 174 [Dempsey Dep. Vol. I at 313:21 – 314:12, 327:8 – 328:21].

168 Ex. 185 [JAN-MS-02987651-656] (12/17 internal SOM workshop); Ex. 193 [JAN-MS-05444748-763] (1/18 evaluation of Janssen's SOM program by The Drug and Chemical Advisory Group).

169 Ex. 185 [JAN-MS-02987651-656 at 651-656]; Ex. 193 [JAN-MS-05444748-763 at 750-763].

170 Ex. 186 [Dempsey Dep. Vol. II at 803:7 – 804:9].

171 Ex. 186 [Dempsey Dep. Vol. II at 551:22 – 552:5, 556:22 – 557:11, 707:10-19, 799:23 – 800:3].

172 Ex. 186 [Dempsey Dep. Vol. II at 487:2-14] ("We have not reported a suspicious order, yes."); Ex. 193 [JAN-MS-05444748-763 at 761].

173 Ex. 193 [JAN-MS-05444748-763 at 761]. Significantly, when Janssen received this report, it reached out to the consultant to request that that sentence be modified or removed. Ex. 198 [JAN-MS-05444648-649].

have been no orders identified as suspicious and thus there have been none reported."[174] But to the contrary, there were many suspicious orders flagged by Janssen's SOM program, some of which Janssen did not appear to investigate before approving the release of the order to the customer.[175] Regardless of whether Janssen ultimately approved or cancelled these flagged orders, all potentially suspicious orders flagged by Janssen's SOM program should have been reported to the DEA. *See Masters Pharm., Inc. v. Drug Enf't Administration*, 861 F.3d 206, 212–13, 215-17 (D.C. Cir. 2017).[176]

The truth of the matter is that Janssen did not want to identify, report, and stop shipping suspicious orders. Instead, Janssen intentionally buried its head in the sand in order to maximize profits. For example, one of Janssen's customers, McKesson Corporation, was found by the DEA to have repeatedly violated the CSA by failing to design and implement an effective system to detect and report suspicious orders for controlled substances distributed to its independent and shall chain pharmacy customers.[177] As a result of those violations, McKesson agreed to pay a $13.25 million civil penalty in 2008 and a record $150 million civil penalty in 2017.[178] As part of its 2017 settlement,

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174 Ex. 198 [JAN-MS-05444648-649 at 648]; Ex. 186 [Dempsey Dep. Vol. II at 492:4-22].

175 *See, e.g.,* Ex. 199 [JAN-MS-02964442 at "Sch. II Call Outs" tab] (in Q2 2015, Janssen's customer, Burlington Drug Co., "had a 420% increase in orders for Schedule II products"; Janssen ultimately approved the order); Ex. 200 [JAN-MS-03739743-744 at 743] (in 3/15, six orders by three customers, including HD Smith and Prescription Supply, were flagged by the SOM program; Janssen decided there was "[n]o need to contact HD and PS" and released all six orders); Ex. 390 [JAN-MS-03739793] (informed at 4:49 p.m. of a flagged order that day from McKesson, who "originally ordered 636 eaches"; Janssen reduced McKesson's order to 288 eaches and approved the reduced order to be released four hours later); Ex. 201 [JAN-MS-03739717-718 at 717] (informed at 4:23 p.m. on Friday, October 3, 2014, of an order from Smith Drug flagged by the SOM program that day for lack of order history within the past year; the order was approved to be released less than five hours later); Ex. 202 [JAN-MS-03739719] (informed at 3:47 p.m. on November 26, 2014, the day before Thanksgiving, of an order from ABC flagged by the SOM program that day for lack of order history within the past year; the order was approved to be released five hours later); Ex. 203 [JAN-MS-02960359-360 at 359] ("There is one suspicious/excessive order for today."; Janssen approved order to be released the following day); Ex. 204 [JAN-MS-02960361]; Ex. 205 [JAN-MS-02960362-363 at 362]; Ex. 206 [JAN-MS-02960364]; Ex. 207 [JAN-MS-02960370-371]. *See also* Ex. 183 [JAN-MS-03124101-110 at 102] (2013 SOM SOP requires the Customer Support Services member "to ensure all Schedule II products remain on hold until they are reviewed for suspicious and excessive ordering").

176 Ex. 180 [JAN-MS-03741170-176 at 171] (2005 SOM SOP requires JOM QA representative "to report any **potentially** suspicious or excessive narcotic orders to the DEA **as identified by this process**") (emphasis added)); Ex. 183 [JAN-MS-03124101-110 at 102] (2013 SOM SOP states that it is "the responsibility of the DEA Compliance Team to review and determine the decision to ship any order identified by this process and to report any **potentially** suspicious or excessive orders to the DEA and/or appropriate state or federal regulatory agency") (emphasis added).

177 Ex. 208 [JAN-MS-02966153-156 at 155].

178 Ex. 208 [JAN-MS-02966153-156 at 155].

McKesson was required to suspend sales of controlled substances from its distribution centers in Colorado, Ohio, Michigan, and Florida for multiple years.[179] After the 2017 settlement was announced, Janssen internally discussed whether McKesson's suspended Ohio distribution center was one to which Janssen shipped its controlled substances and what precautions should be taken to ensure Janssen did not ship to a location that is no longer allowed to sell controlled substances.[180] JOM's Senior Planner for McKesson explained how Janssen had worked around that issue to ensure it could continue selling McKesson controlled substances:

> JOM ships Scheduled products/Controlled Substances to McKesson's RDC (Regional Distribution Centers, Olive Branch, MS) and RDC distributes down to their forwarding DCs. So from JOM perspective, we do NOT sell/ship Scheduled products/Controlled Substances direct to McK forwarding DCs.[181]

Thus, despite knowing that its controlled substances would eventually reach McKesson's forwarding distribution centers and that some of those centers could no longer sell controlled substances, Janssen disclaimed any responsibility for ensuring that its controlled substances were not sold to the suspended distribution centers.[182]

F. Allergan Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Allergan and its SOM system are descended from Watson Pharmaceuticals, Inc. ("Watson"), Actavis, Inc. ("Actavis"), which Watson bought in 2012-2013, and Allergan, which the merged companies then bought in 2015.[183] Neither of the two prior companies, or the merged group, maintained effective controls against diversion.

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179 Ex. 208 [JAN-MS-02966153-156 at 155].

180 Ex. 208 [JAN-MS-02966153-156 at 154]; Ex. 174 [Dempsey Dep. Vol. I at 289:14 – 292:9].

181 Ex. 208 [JAN-MS-02966153-156 at 153]; Ex. 174 [Dempsey Dep. Vol. I at 292:11 – 293:2].

182 Ex. 208 [JAN-MS-02966153-156 at 153].

183 See, Ex. 480 & Ex. 481 (Press Releases dated Jan. 23, 2014, June 15, 2015) Through a 2013 acquisition, the company had become a "plc" and moved its headquarters to Ireland to take advantage of "a favorable tax structure" but kept its executive headquarters in New Jersey, USA. *See* https://www.Allergan.com/news/news/thomson-reuters/actavis-to-acquire-warner-chilcott-to-create-premi

1. *Pre-Merger Actavis employees repeatedly recognized the Company failed to maintain effective controls against diversion*

Before the year-end 2012 merger, Actavis produced twelve different generic opioids including some of the most abused and diverted opioids such as generic OxyContin (Oxycodone I hydrochloride tablet), generic Opana ER (Oxymorphone tablet) and generic Duragesic (a fentanyl transdermal patch). *See* Ex. 483 (Allergan Kaufhold Ex. 3 at 4) (listing the Amended New Drug Application ("ANDA") number for each of the pre-merger Actavis generic opioids). Pre-merger Actavis maintained same rudimentary threshold-based SOM system in place from November 2000 through October 2012.[184] Under that system, the Customer Service group printed a report "several times a day" showing any controlled substance order that was "25% over the customer's rolling average" of orders placed over the prior six months. Ex. 486 (Woods Depo. Ex. 12) at 2. Then, according to an internal document, "Customer Service reviews (eyeballs) the suspicious order report throughout the day (when a new report is created)" and "any order that looks unusual is investigated and any unusual items are cleared before the order is released." *Id.* In February 2009, Senior Manager of Actavis's Customer Service Department, Nancy Baran told her boss that the existing Actavis process was inadequate to "prevent shipping excess product" because it was not cumulative and because there were too many orders over the 25% threshold. Ex. 487 (Allergan_MDL_02128035). Baran remembered only one order between 2008 and 2017 that was ever deemed to be suspicious and reported to the DEA as such, but testified she did not "know any details about it." Ex. 489 (Baran Deposition, 303:7-304:10). All other pended orders were cleared and released. *Id.*

The 2000-2012 Actavis system only flagged orders unusual in size; it did not flag orders unusual in frequency or pattern in real time. The system did not utilize any downstream customer information available to Actavis, did not differentiate among NDC codes for drugs with a higher risk

[184] See Ex. 484 (Woods Depo. Ex. 12 (Allergan_MDL_02081243)); Ex. 485 (Ex. 13 (Allergan_MDL_02128514)). Mary Woods served as the Corporate Representative of the Allergan Defendants with regard to Suspicious Order Monitoring issues. The first 24 exhibits to her deposition are the SOM SOPs the Allergan Defendants said were in place.

of diversion, and did not automatically stop orders from shipping. Although Actavis mailed reports to the DEA of orders that were identified in the system from 2009-2012, the lack of any analysis of such data made the reports meaningless. The system was not an effective control and Actavis employees recognized as much. Yet the system remained in place until 2012.[185]

In September 2012, Actavis was implementing a statistics-based more modern SOM system designed by the Buzzeo/Cegedim group to detect "orders of interest" in "Direct Customer sales." Ex. 492 (Woods Depo. Exhibit 15 (Allergan_MDL_01684748)). On October 1, 2012, it began working alongside Actavis's prior system.[186] Until that date, the company had used the SOM system as described in November 2000.[187]

At the same time Actavis was preparing to implement the Buzzeo/Cegedim SOM system, its personnel were called to meet with the DEA. On September 12, 2012, five Actavis employees met with the seven DEA personnel at its Arlington, Virginia office for about three hours to discuss opioid diversion. At the meeting Barbara J. Boockholdt, Chief, Regulatory Section, told the Actavis employees that its products were being distributed in Florida in quantities and under circumstances highly suggestive of diversion. Ex. 496 (US-DEA-00000001). Leonard Levin, Staff Coordinator of the DEA Regulatory Section told Baran that:

- "Actavis should send someone from their compliance team to visit pharmacies who were receiving their products in south Florida, in order for them to witness the long lines at pain clinics, out of state license plates, questionable

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185 A separate program from January 2011 designed by Actavis's marketing group, tracked only "oxycodone IR suspicious orders." Ex. 490 (Woods Depo Ex. 14 (Allergan_MDL_00490306)). The marketing program compared monthly order rates and noted "any individual customer locations that have ordered 50% or greater than their established six month order average." *Id.* It was not designed to track any DEA regulations, and after three months of trials, it was apparently abandoned. Ex. 388 (Acquired_Actavis_00665233) (March 24, 2011 email discussing SOP).

186 Ex. 493 (Allergan_MDL_03380778) (Thursday October 4, 2012 email noting that "we went live on Monday with our enhanced Suspicious Order Monitoring" system).

187 A separate system, titled "Indirect Customer Sales" also was issued in late 2012. Ex. 494 (Woods Depo. Exhibit 16 (Allergan_MDL_01979834)). This SOP, which was to focus on customers of Actavis's direct customers using chargeback and other data, was never implemented. As the contemporaneous notes of a Watson employee noted, Actavis assigned "no resources," or personnel, to carry out the indirect SOP. Ex. 495 (Woods Depo. Ex. 36 at 12 ("Also prepared to work on the indirect side, no resources but have SOP's – work has been completed already")).

clients, security guard(s) in the parking lots, and signs stating cash payment only."

- Actavis employees should "get to know their customers, visit distribution sites, visit customers of those distributors, check on customers' suspicious order monitoring systems, review due diligence files, and obtain printouts of pharmacies or practitioners who are receiving Actavis products."
- "[I]f their customers refused to provide them with sales information Actavis should consider cutting them off."
- "Actavis [should take a] serious look at their quota request, review their suspicious order monitoring system, visit their customers to review their suspicious order monitoring systems as well as their due diligence files, ask to see their customers' top customers for Actavis products, and contact their local DEA Office with any questions or issues."

Id. The DEA presentation included slides "compiled from ARCOS reports [Actavis had] previously submitted to DEA" showing the massive amount of Actavis opioids being shipped to Florida compared to other states. *Id.* at 92. One slide, for example showed that 2011 sales of Actavis's 30 mg Oxycodone (generic OxyContin) were six times higher in Florida than in the next highest state. *Id.*

Actavis's Ethics & Compliance Officer, Michael R. Clarke, testified that the meeting was "ostensibly for the DEA to talk to us about our anti-diversion efforts," but that "the tone and the tenor of the meeting . . . made it less productive than it could have been" because, instead of treating the Actavis individuals "as professionals," the DEA looked at and talked to the Actavis representatives "as street dealers." Ex. 497 (Clarke Depo., 86-89). "[T]hey described it," Clarke continued, "without using these specific words, but in a way that we would just manufacture, put the product out on the street, and not have a care as to where it went" and "described finding or seeing or obtaining product, you know, opioid products that seemed to be diverted relatively easily." *Id.* at 90-91. In late October 2012, Actavis had a follow-up meeting with two field representatives from the DEA's Newark, New Jersey office where, according to Clarke, DEA requested a reduction of approximately 30%-40% in Actavis' manufacturing quota for oxycodone. *Id.* at 98-102. According to Clarke, Actavis' then CEO, Doug Boothe, rejected the DEA's request. *Id.* at 103-104.

Boothe has testified that he believed Actavis' responsibility was only to making certain that orders were received from licensed pharmacies and were within numerical thresholds, and that Actavis had no responsibility (or accountability) for preventing diversion:

> Again, I don't think we had responsibility for, accountability for preventing diversion. We had responsibility and accountability for making certain that the orders that we received were valid from licensed pharmacies and were within our suspicious order monitoring thresholds as it was described earlier then with the Buzzeo model or the more statistical model. So we -- that was our responsibility. Once it goes outside of our chain of custody, we have no capability or responsibility or accountability to -- or at least my understanding, I'm not a lawyer, as it relates to diversion. So, once we ship a valid order to a wholesaler or ship a valid order to a distributor or another smaller wholesaler, our chain of custody is finished at that point.

Ex. 498 (Boothe Depo., 408-09).

2. *The Pre-Merger Watson SOM was even more rudimentary than Pre-Merger Actavis's*

The core of the pre-merger Watson SOM system, like the early pre-merger Actavis system, dated to the early 2000s. Ex. 499 (Woods Depo. Ex. 1 (Allergan_MDL_01844864)). A 2001 memo says Watson's inventory system automatically compiled a "12-month average" of customers' various orders, and reported violations of it Customer Service personnel (also known as the "Call Center" group). *Id.* A May 2004 Operational Procedure added a "SOMS multiplier table" to the system that increased the level at which the inventory system would alert a potentially suspicious order. Ex. 500 (Woods Depo. Ex. 3 (Allergan_MDL_01839001)). The multiplier, set by people instead of an algorithm, placed a different value for various "classes of trade," and orders from wholesalers, distributors and chain pharmacies were regularly allowed at triple the historical average, or more.[188]

The Watson system affirmatively allowed customers to get around violations by canceling the order, or cutting the quantity. Ex. 503 (Allergan_MDL_01838989) at '9001. Mary Woods, who was in charge of the Watson SOM system, stated that Watson "never needed to file a report" because they

[188] Ex. 501 (Allergan_MDL_02181123 at '1150)(noting that the "SOMS Multi" for wholesalers was "3"); see also *Id.* at '1131 (noting that the "SOMS Multi" for "chain" stores was "6"). The wholesaler/distributor and chain store multipliers apparently covered "99 percent of the orders" in the system. Ex. 502 (Allergan_MDL_02578082)

would cut or cancel the order instead.[189] This policy was consistent through 2012.[190] In 2012, Watson merely required that "[i]f the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation." Ex. 506 (Allergan_MDL_01175574) at '81. Before the merger with Watson, Actavis policy did not allow reducing or cancelling an order.[191] After the merger, the combined company adopted the Watson SOM system, and cutting or cancelling was not generally prohibited. Watson also allowed orders to be shipped based on "an employee inside of the company [including salespeople] providing the justification" in "an email." Ex. 508 (Woods Depo. I, 140:3-141:9). Watson Call Center/Customer Relations Operation did not add any new staff to handle the SOMs "validations" between 2009 and 2012, but the number of validations increased substantially. Ex. 509 (Woods Ex. 35 at Allergan_MDL_03802654). In 2009, each "administrator" handled an average 62 "SOMs validations" per month. *Id.* at 2660. In 2010, that number jumped to an average of 180, and in 2011 the number reached 280, a 350% increase over 2009. *Id.* Woods, who oversaw the system, did not seek to add more personnel at any time.[192]

Like Nancy Baran at Actavis, Thomas Napoli, Watson's (and then post-merger Actavis's) DEA Compliance Chief, made clear that the system did not comply with the DEA laws and regulations. In November 2008 Napoli wrote a memo stating that "[i]t is highly recommended that industry utilize a 'total SOM model.' This model favors a more statistically-based model that dynamically evaluates a variety of order characteristics to determine whether an order should be

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189 Ex. 304, Woods 1/10/19 Depo. at 25:18-31:16; Ex. 386, Woods Depo. Ex. 30 ("[a]ny time there was a question during the order process of a suspicious order quantity, we went (and still follow the same procedure) back to a customer to let them know we would need to notify the DEA due to the quantity they wanted to order. In response, they either reduced the quantity or cancelled the order").

190 Ex. 504 (Allergan_MDL_02146521) at 2 (July 2011 SOM policy); *see also* Ex. 505 (Allergan_MDL_03952774) at 9 (April 2007 SOM policy); Ex. 500 (Allergan_MDL_1839002) at 2 (May 2004 SOM policy).

191 Ex. 507 (Allergan_MDL_03368470) (Baran PowerPoint presentation making clear that "'Cutting' orders to a volume that puts the order under a threshold is not acceptable," and that the "DEA has stated on this topic, 'That is like saying a little bit of diversion is okay'").

192 *See e.g.* Ex. 510 (Woods Ex. 33, Allergan_MDL_02187056 at 7060)(noting static headcount in "SOMS Admin" and "Order Administration-Support").

pending. Characteristics include order size, ordering frequency, ordering patterns and percentage of CS ordered." Ex. 511 (Napoli Depo. Ex. 1 (Allergan_MDL_0353513)). He continued that "[t]his approach is viewed to be more effective and defensible than the traditional approach of just setting a threshold." *Id.*

Starting in 2011, Napoli advocated to hire Buzzeo/Cegedim to create a new system, just as Baran had at Actavis. Napoli wrote that, among other things, the requirement of "manual effort is very labor intensive, as the current system is not configured with any analytical tools to support timely and accurate decision making. This approach also introduces the element of 'human interaction' in the order evaluation process." Ex. 512 (Allergan_MDL_02467540) at '46. A 2012 PowerPoint from Napoli's files notes that Cegedim had "produced a written report" and under "Findings" noted that the multiplier threshold was "not consistent with specific requirements noted within regulations and guidance," that Watson's system "evaluates at SKU level," left open the "possibility of distributing orders across multiple SKU's without detection," and that Watson's system did not "evaluate listed chemicals." Ex. 513 (Allergan_MDL_02468983) at '87-89. The PowerPoint made "Recommendations" including developing an SOM system to "Fully address specific regulatory requirements," and that system was "Budgeted for 2012 Implementation." *Id.* at '90-91. But the new system was never implemented, and when Watson bought Actavis, the combined Company reverted to the Watson system until 2015 when it announced it was selling all of its generic drugs and various corporate subsidiaries to Teva, and as Napoli said, Teva "already had their own program in place for Suspicious Order Monitoring." Ex. 514 (Napoli Deposition at 324:3-12); After the sale, Napoli said, he "was laid off." *Id.* at 325:19.

Like the pre-merger Actavis system, the automated portion of Watson's system only looked for orders of unusual size and not for frequency and/or pattern. The rigid formula used did not satisfy DEA requirements to detect and investigate suspicious orders. The automated portion of the system

did not utilize any downstream customer information available and did not differentiate among NDC codes for drugs with a higher risk of diversion. The companies' failure to identify suspicious orders was known among their employees. The SOM was not an effective control and the Watson and Actavis employees recognized as much. Yet the system remained in place until 2016, and was not replaced. Now, Allergan asserts that as a "virtual manufacturer" that outsources its manufacturing, transport and delivery systems, it is no longer a DEA registrant with regard to Kadian and Norco, and need not have a suspicious order monitoring system at all.[193] Yet no category of "virtual" manufacturers exists, and Allergan cannot delegate its duties to prevent diversion.

G. Cardinal Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Cardinal, too, has admitted that it failed to comply with the requirements of the CSA. In a May 2012 agreement with the DEA, Cardinal stated that it "admits that its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." Ex. 209 (CAH_MDL2804_02465983). Nor is there any dispute that, prior to January 2008, Cardinal also failed to meet its duties under the CSA to maintain effective controls against diversion.

In a January 2008 email to Cardinal leadership, then-CEO Kerry Clark called for more accountability from Cardinal management regarding regulatory compliance. In the 18 months leading up to the CEO's email, Cardinal Health had accumulated nearly $1 billion in "fines, settlements, and lost business" as a result of multiple regulatory actions, including the suspension of Cardinal distribution centers' licenses for failure to maintain effective controls against the diversion of opioids. Mr. Clark noted that the company's "results-oriented culture" was perhaps "leading to ill-advised or short-sighted decisions."[194] As set forth below, the corporate mindset described by Mr. Clark was

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193 *See e.g.,* Ex. 515 (Acquired_Actavis_01843335) (discussing regulation of entities that refer to themselves as "virtual manufacturers").

194 Ex. 210 (CAH_MDL_PRIORPROD_DEA07_00827893).

confirmed by the underfunded, understaffed, and under-developed suspicious order monitoring system in place at that time.

Mr. Clark's January 2008 call for change was not the first time Cardinal management raised the issue of the company's apathy toward regulatory compliance. In a January 2005 Cardinal presentation regarding Cardinal's Quality and Regulatory Affairs (QRA) department, it was noted that "[q]uality is not a mindset at Cardinal health – we are not proactive" and "[t]his is not high enough priority today[.]"[195] The presentation further describes QRA as being "[u]nder resourced today" and that there were "[n]ot enough people."[196] The problems highlighted in the 2005 presentation went ignored. In a year-end review of Cardinal's compliance budget for the 2006-2007 fiscal year, it was noted that QRA staff workloads were at "full capacity," that "[e]ffective management of current projects and initiatives is difficult," and that the company lacked resources "to improve and enhance existing programs."[197] In a January 7, 2008 email to members of Cardinal's Anti-Diversion Steering Committee, Vice President of Retail Marketing, Steve Lawrence, voiced his concern that QRA did not have sufficient resources.[198] Then on January 26, 2008, Lawrence provided an update regarding Cardinal's efforts to staff its QRA department and stressed that the staff was working "day, night, and weekends" but that the group remained understaffed.[199]

With Cardinal's lack of resources for regulatory compliance, it is no surprise that in late 2007 and early 2008 the DEA served immediate suspension orders or orders to show cause on four Cardinal distribution centers in Washington, Texas, Florida, and New Jersey for distributing opioids to pharmacies Cardinal knew, or should have known, were diverting opioids.[200] The DEA's action

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[195] Ex. 211 (CAH_MDL_PRIORPROD_DEA07_01181262, 01181325).

[196] *Id.*

[197] Ex. 212 (CAH_MDL2804_02102331, 02102332).

[198] Ex. 213 CAH_MDL_PRIORPROD_DEA07_00884713.

[199] Ex. 214 (CAH_MDL_PRIORPROD_DEA07_00875539, 00875540).

[200] Ex. 215 (CAH_MDL_PRIORPROD_DEA12_00013056).

resulted in a Settlement and Release Agreement and Administrative Memorandum of Agreement (2008 MOA) that covered, *inter alia*, the "alleged failure of Cardinal to maintain adequate controls against the diversion of controlled substances, on or prior to September 30, 2008, *at all distribution facilities* … operated, owned, or controlled by it," which includes the Wheeling, West Virginia distribution center that services CT1 counties.[201]

The DEA's 2007/2008 action should not have been a surprise to Cardinal because before 2008, Cardinal did not have a suspicious order monitoring system in place that would allow it to sufficiently detect and report suspicious orders of opioids. In 2005, Cardinal Health VP of Health System Sales, Mark Mitchell, stated that to his knowledge Cardinal did not have a "specific protocol to monitor possible drug diversion (outside of ARCOS) activity with internet pharmacies or wholesaler [accounts]." [202] Cardinal simply did not monitor what these accounts purchased. Nearly three years later, in a January 2008 email chain regarding whether Cardinal could continue to distribute to a Minneapolis internet pharmacy (it was believed that the pharmacy did not order controlled substances) counsel for Cardinal reminded VP of Anti-Diversion and Supply Chain Integrity, Michael Moné, that Cardinal "does not yet have a system for detecting all suspicious orders."[203]

As more fully described below, prior to 2008, Cardinal primarily reported suspicious orders to the DEA after they had already been shipped in the form of monthly summaries called Ingredient Limit Reports (ILRs). ILRs accounted only for the volume of a drug purchased and were not able to track unusual patterns or frequency. Each of Cardinal's more than two dozen distribution centers manually submitted hard copies of ILRs to the DEA every month, which contained information related to thousands of orders. Cardinal failed to provide the resources necessary to even review its

[201] Ex. 215 (CAH_MDL_PRIORPROD_DEA12_00013056, 00013058, 00013068) (emphasis added).

[202] Ex. 216 (CAH_MDL_PRIORPROD_DEA07_00318789).

[203] Ex. 217 (CAH_MDL_PRIORPROD_DEA07_00968964).

own ILRs.[204] Cardinal Health's former VP of QRA, Steve Reardon, testified that at a company with 30,000 employees, Cardinal tasked just three employees with reviewing ILRs. Reardon agreed that three individuals for such a task was insufficient.[205]

In 2007, Cardinal hired Cegedim Dendrite (Dendrite) to conduct an audit of its Suspicious Order Monitoring system. With respect to Cardinal's ILRs, Dendrite found that because the reports were based on historical information, they are "not sufficient to monitor deviations in ordering patterns on a real time basis" and that the ILRs "do not substitute for real time automated analysis of pattern and frequency."[206] However, Cardinal, by its own admission, did not have a policy to stop shipment of suspicious orders until 2008. As described more fully below, for more than a year, Cardinal knowingly violated the CSA's "shipping requirement" by reporting suspicious orders via ILRs, shipping the suspicious orders prior to reporting them, and conducting no due diligence to dispel suspicions of diversion.

It was not until after the DEA suspended its distribution center licenses in 2007/2008 that Cardinal took steps to implement an electronic suspicious order monitoring program.[207] In 2007, Cardinal hired Deloitte to create a threshold system, which set thresholds for each base code for each customer based on the customer's designation as small, medium, or large (based on sales) and the average orders for the prior year of all customers in that size designation multiplied by a factor of three.[208] Deloitte's calculation of initial thresholds was based on the previous twelve months' worth of

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[204] Ex. 218, Reardon Dep., 71:16-72:5; 147:14-21.

[205] *Id.* at 464:4-20.

[206] Ex. 219 (CAH_MDL2804_03309960).

[207] Prior to this time "there was no electronic system for analyzing orders" and "most of the files on customers and orders were on paper, rather than electronic[.]" *See* April 12, 2013 Investigation Report of the Special Demand Committee of the Board of Directors of Cardinal Health, Inc., Ex. 220 (CAH_MDL_PRIORPROD_HOUSE_0003331, 0003341).

[208] Deloitte Procedure for Threshold Limit Determination, Ex. 221 (CAH_MDL_PRIORPROD_DEA07_00950932).

ordering data. These numbers were significantly inflated due to the fact the United States was already in the middle of the deadly opioid epidemic.[209] Cardinal Health took no steps to consider the opioid epidemic when setting or increasing these thresholds.

In late 2012, Cardinal's relationship with Deloitte was coming to an end. For the previous 4-5 years, Deloitte advised Cardinal Health regarding the development of its suspicious order monitoring system. Emails among Deloitte employees indicate hesitation to end the relationship as Cardinal had not implemented many of the changes Deloitte suggested and Cardinal's sense of urgency to do so "if not gone completely, at least was invisible."[210] The Deloitte emails describe Cardinal repeatedly pushing back deadlines on implementing critical changes to its suspicious order monitoring system and Deloitte employees described the "situation" at Cardinal as chaotic.[211]

After 2008, Cardinal ceased submitting ILRs as its suspicious order reports, but continued to manually submit suspicious order reports. Cardinal documents indicate that, nationwide, Cardinal reported only a few dozen suspicious orders per year from 2008 to 2013.[212] The Baltimore, Maryland DEA office found that between 2008 and October 1, 2011, Cardinal's Swedesboro, New Jersey distribution center failed to report any suspicious orders while shipping many orders that were suspicious.[213]

As an additional indication of its failure to maintain effective controls against diversion, Cardinal provided preferential treatment to chain pharmacies, treating them differently than retail-

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[209] Mark Hartman, who was appointed by Cardinal in December 2007 to the position of Senior VP of Supply Chain Integrity and Regulatory Operations for Healthcare Supply Chain Services (HSCS), "responsible for leading HSCS's initiative to build state of the art diversion prevention, supply chain integrity and regulatory compliance processes and systems" testified that he was aware of the opioid epidemic in 2007. Ex. 222, Hartman Dep. 19:1-20:12; 322:4-8. *See also*, Ex. 223 (CAH_MDL2804_00225021), November 6, 2008 presentation by Mark Hartman regarding "Supply Chain Integrity."

[210] Ex. 224 (DC00120560, 120561).

[211] *Id.*

[212] Ex. 225 (CAH_MDL2804_03262274, 03262438.

[213] Ex. 227 (CAH_MDL2804_02509732, 02509741).

independent pharmacies with respect to setting thresholds and conducting due diligence. Cardinal refused to impose the same requirements on chain customers that it did on retail-independents because, as stated in Cardinal's June 27, 2006 letter to the New York Attorney General, large, national pharmacy chains can "take their billions upon billions of dollars in business to any wholesaler in the country."[214] Cardinal did not calculate thresholds for chain pharmacies in the same manner described above; instead, it merely adopted a standard threshold for the entire chain.[215] Cardinal also failed to conduct due diligence on its retail pharmacy chain customers, and instead, relied on the chains' in-house loss prevention departments to report this information. Cardinal did not, however, make any effort to evaluate chain pharmacies' anti-diversion programs.[216] Former Cardinal Health Director of Supply Chain Integrity, Steve Morse, confirmed this practice, particularly with respect to CVS.[217] Morse testified that despite Cardinal's written policy requiring pharmacies to provide drug utilization reports, controlled and non-controlled substances sales data, and prescriber information, and that a pharmacy's refusal to provide such information would be a red flag, CVS refused to provide this information despite multiple requests. Despite the clear violation of Cardinal's own policies, Cardinal continued to supply CVS stores with huge volumes of opioids.

In 2012, the DEA began another prosecution of Cardinal for failing to prevent diversion and for not complying with the 2008 MOA.[218] The DEA served another Immediate Suspension Order (ISO) on Cardinal's distribution facility in Lakeland, Florida – one of the facilities at issue in the 2008 action – for distributing excessive amounts of oxycodone to retail pharmacies, including some chain

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[214] Ex. 228 (89(5) FOIL Appeal G000804 000006).

[215] Ex. 220 (CAH_MDL_PRIORPROD_HOUSE_0003331, 0003345).

[216] Ex. 229, Deposition of Todd Cameron, 347:16-348:15 (CAH_MDL2804_02953369, 02953715-6).

[217] Ex. 230, Deposition of Steve Morse, 113:8-13.

[218] The DEA's many prosecutions of Cardinal belie the opinion of Cardinal's expert Brian H. Reise that Cardinal was at all times in compliance with its CSA duties. *See* Ex. 231, Reise Expert Report. Indeed, Because no reasonable jury could credit Mr. Reise's opinions that contradict the official actions of the DEA during the relevant time, the Reise Report is insufficient to create a triable issue of fact.

stores.[219] Steve Morse, who Cardinal hired following the 2008 MOA, was demoted for failing to timely terminate pharmacy customers despite finding evidence of suspected diversion. Morse was removed from his position as a Director of Investigations to a position in regulatory management. A 2013 report of the Special Demand Committee of Cardinal Health's Board of Directors cited Morse's questionable judgment as part of the reason for this demotion and the fact that he failed to review pharmacy site visit reports as required by Cardinal's 2008 Standard Operating Procedures.[220] Similarly, as a result of the 2012 ISO and DEA investigation, Michael Moné was moved from his position as Vice President of Anti-Diversion into a position as an attorney with the company's regulatory group. The Special Demand Committee report states that Mr. Moné was moved as part of Cardinal's transition to "assessing customers based more on objective criteria;" under Moné evaluation of customers was a subjective standard.[221]

In response to the 2012 DEA investigation, Cardinal admitted that it failed to comply with the 2008 MOA and had not engaged in proper due diligence in evaluating its customers for diversion. The DEA testified, through Thomas Prevoznik, that it was "in fact frustrated that registrants were blatantly violating the MOUs[/MOAs] from prior administrative actions" including "Cardinal Health's 2008 MO[A] and settlement which resulted in a second DEA fine."[222] I

Complying with the Controlled Substances Act was simply not a priority at Cardinal Health. It is this mindset that led to the following failures for which Plaintiffs seek partial summary judgment finding that Cardinal violated the Controlled Substances Act.

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[219] Ex. 209 (CAH_MDL2804_02465982).

[220] Ex. 220 (CAH_MDL_PRIORPROD_HOUSE_00003331, 0003367).

[221] Ex. 220 (CAH_MDL_PRIORPROD_HOUSE_0003331, 0003367).

[222] *See* Ex. 10, Prevoznik Dep., Vol. II, 621:5 to 621:20.

1. Cardinal Allowed Suspicious Orders to Ship Without First Conducting Due Diligence to Determine the Orders Were Not Likely to be Diverted

Prior to 2008, Cardinal Health did not have a system in place to timely report suspicious orders or prevent suspicious orders from being shipped to customers in CT1 jurisdictions. Despite purportedly identifying hundreds of suspicious orders in CT1, Cardinal only reported the orders to the DEA after they had shipped, without first conducting any due diligence to dispel suspicions of diversion.

From at least the mid-1990's until 2008, Cardinal relied on the submission of ILRs to identify and report suspicious orders.[223] Each of Cardinal Health's more than two dozen distribution centers submitted an ILR to the DEA every month. Cardinal has produced ILRs that were purportedly submitted to the DEA by the Wheeling, West Virginia distribution center[224] for each month from August 2005 through December 2007 and April 2008.[225]

Each ILR contains information regarding Cardinal Health customers who purchased controlled substances in excess of a pre-determined limit applicable for that month. Each ILR identifies the pharmacies' address, DEA number, dates of each order of controlled substance for the month, the dosage amount (*e.g.*, 20 milligrams, 40 milligrams, 80 milligrams), and the size of each order (*e.g.*, number of pills). If a customer is included in an ILR, it is because for that month the customer's total orders of a particular drug exceeded the limit for that drug base code.[226] The ILRs include all

[223] Ex. 218, Reardon Depo., 424:9-17; 425:2.

[224] From 2006 to 2017, the Wheeling facility shipped over 99% of opioids/opioid products to customers in Cuyahoga and Summit Counties. *See* Ex. 232, Cardinal Health's Written Response to Plaintiffs' Second 30(b)(6) Notice, Topic 2.

[225] For nearly all months, Cardinal produced to Plaintiffs what appears to be duplicates of the same ILR. Duplicates are included in this chart for the sake of completeness.

[226] The base code for oxycodone hydrochloride, for example, is 9143, codeine is 9050, and hydrocodone is 9193.

orders of the drug base code by a given customer for that month, and the orders in excess of the limit were considered suspicious orders by Cardinal.[227]

ILRs were retrospective, detailing orders for the previous month, and were submitted to the DEA after the month ended and after the identified orders had been shipped to their respective customers.[228] In other words, Cardinal was reporting suspicious orders to the DEA well after they had already been shipped and without conducting any due diligence to dispel suspicions of diversion.

This is hardly surprising, given that Cardinal did not have a policy of halting suspicious orders until 2008 when it began utilizing a threshold system. By Cardinal's own admission, it was knowingly shipping orders it had identified as suspicious to pharmacies in Summit and Cuyahoga Counties until 2008. These shipments, alone, are sufficient to establish that Cardinal shipped opioids in violation of the CSA – but they are not Cardinal's only violations.

2. Cardinal Failed to Report Suspicious Orders

Between 2012 and 2015, Cardinal failed to report more than 14,000 suspicious orders to the DEA, the majority of which included orders for opioids and at least four orders from customers in CT1 jurisdictions. On September 26, 2018 the Montana Attorney General deposed Cardinal employee, Todd Cameron, pursuant to an investigative subpoena. Clarifying earlier testimony, Mr. Cameron explained that in 2018 Cardinal met with DEA to "talk about suspicious orders that [Cardinal] had identified internally" that "did not get reported to DEA."[229] Mr. Cameron testified that from 2012 through 2015 there were approximately 14,000 suspicious orders from "across the country" that Cardinal failed to report to the DEA and that the "vast majority" of those orders involved opioids.[230]

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[227] Ex. 218, Reardon Depo., 426:16-427:4; *see also* Ex. 233, Cardinal Health's Supplemental Response to Plaintiffs' Combined Discovery Request No. 3.

[228] Ex. 218, Reardon Depo., 427:17-428:6.

[229] Ex. 229, Cameron Depo., 268:21-269:3.

[230] *Id.* at 269:12-270:13.

Cardinal "uncovered" the unreported suspicious orders retrospectively through an audit process put in place in 2015.[231] At least four of these orders were placed by customers in CT1 jurisdictions.[232]

Through its 30(b) designee, Cardinal Health testified that the CSA's reporting requirement has been "in place since 1971 and applicable to Cardinal Health as modified by the guidance provided by the DEA over the years."[233] Cardinal's failure to report more than 14,000 suspicious orders to the DEA between 2012 and 2015 is a clear violation of the CSA, and Plaintiffs seek partial summary judgment finding that Cardinal so violated its duties under the CSA.

H. McKesson Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

McKesson's systemic failure to follow the CSA requirements has been documented in two large settlements with the DEA and has been conceded by its corporate designee, Nate Hartle during his 30(b)(6) deposition when he testified that as a result of its conduct McKesson accepts partial responsibility for the societal costs of the opioid epidemic this country faces today. (*See* 7/31/18 Hartle Dep. at 285:6-286:15, Ex. 12). Indeed, in January 2017 settlement with the DEA, McKesson accepted responsibility for violating the CSA and expressly acknowledged that:

> at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 8942(a)(5).

Ex. 249 (2017 Settlement Agreement at p. 5) Based on this acknowledgement alone, Plaintiffs believe that this Court can find, as a matter of law, that McKesson violated the CSA. Moreover, as is demonstrated below, McKesson failure to comply with the basic CSA requirements is supported by ample additional documentary evidence and sworn testimony.

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[231] *Id.* at 271:18-22.

[232] *See* Ex. 229, Cardinal's Written Response to Plaintiffs' Second 30(b)(6) Notice, Topic 16, n. 1.

[233] Ex. 11, Depo. of Norris, 65:20-66:2.

1. McKesson's SOM Programs Prior to 2008 Were Wholly Inadequate and Failed to Comply with the Requirements of the CSA

(a) McKesson's "Section 55" Program Was a Rudimentary System that Failed to Meet the Most Basic CSA Requirements.

From at least 1997[234] until May 2007, the sole system utilized by McKesson to identify and report suspicious orders of controlled substances, including opioids, was found in Section 55 of the McKesson Drug Operations Manual. Under this system, McKesson produced daily and monthly reports – known as DU-45 reports – that documented retrospective sales of controlled substances when those sales exceeded three times of that customer's 12 month purchase average for that drug base code. Ex. 237 & Ex. 238 (MCKMDL00651873 at 00651919-20; 1/10/19 Gary Hilliard Depo. at 163:21-169:7).[235]

McKesson's own regulatory employees have acknowledged that this system did not flag true suspicious orders, as required by the CSA. McKesson's Regulatory Affairs Director, David Gustin, noted "the previous reports [DU-45] were not the exclusive and proper response to this regulation. We have an obligation to report 'suspicious orders.' … Simply reporting larger than usual orders does not when there are so many plausible and routine reasons for orders to be 'larger than normal.'" Ex. 240 (MCKMDL00510747). Similarly, another Director of Regulatory Affairs for McKesson, Gary Hilliard, has testified that McKesson's suspicious order monitoring system prior to 2007 was not designed to detect true suspicious orders. Ex. 238 (1/10/19 Gary Hilliard Depo. at 176:8-176:22). Instead, this system was focused solely on reporting excessive orders, which is not consistent with the requirements of the CSA.

Of equal importance, Section 55 included no requirement to block orders that were deemed excessive and ultimately reported to DEA. In fact, McKesson made no effort to block suspicious

[234] The earliest CSA compliance-related SOP produced by McKesson is from 1997. (*See* Ex. 237, MCKMDL00651873).

[235] However, it should be noted that McKesson has not been able to locate any DU-45 reports that were allegedly generated from the New Castle Distribution Center, which was the distribution center that serviced Summit and Cuyahoga Counties. Ex. 239 (*McKesson Corporation's Second Supplemental Objections and Responses to Plaintiffs' Combined Discovery Requests* at p. 10).

opioid orders until it began utilizing the Controlled Substances Monitoring Program in May 2008. Ex. 238 (1/10/19, Gary Hilliard Depo. at 52:21-53:3). Similarly, outside of confirming erroneous "fat fingered" orders, McKesson undertook no investigation of the legitimacy of excessive orders under the Section 55 program either. Ex. 241 (11/8/18, Blaine Snider Depo. at 77:3-78:4).

The massive shortcomings of Section 55 were perhaps best illustrated in DEA's investigation into large shipments of opioids provided by McKesson to rogue internet pharmacies in 2005 and 2006. In late 2005, DEA began investigating McKesson for filling large quantities of hydrocodone and oxycodone orders for rogue internet pharmacies. In January 2006, DEA notified McKesson that it had identified more than 2 million doses of hydrocodone delivered by McKesson to several rogue internet pharmacies during a 3 week period. Ex. 242 (MCKMDL00496876 at MCKMDL00496877).[236] Importantly, during discussions with DEA, McKesson conceded that these extremely large orders were not flagged under its Section 55 system, in part, because McKesson did not track the sale of generic drugs for suspicious order monitoring purposes under that system. Ex. 242 (MCKMDL00496876 at MCKMDL00496877 - MCKMDL00496878).

(b) McKesson's Short-Lived Lifestyle Drug Monitoring Program Did Little to Improve Upon Section 55's Shortcomings.

In May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP"). The LDMP was limited to four drugs (oxycodone, hydrocodone, alprazolam and phentermine). Ex. 243 (MCKMDL00355251). For these four drugs, an 8,000 monthly dosage unit threshold was set for every McKesson customer nationwide. Ex. 243 (MCKMDL00355251). Once the 8,000 dosage unit threshold was met in a given month, a 3 level review process was to be triggered. Ex. 243 (MCKMDL00355251 at MCKMDL00355252-00355255).

McKesson represented to DOJ that under the LDMP "customers will not be allowed to exceed the 8,000 monthly dosage limit until a due diligence review has been completed." Ex. 245

[236] During his transition from DEA to McKesson in 2013, Gary Boggs confirmed that the pharmacies at issue in DEA's 2006 investigation were in fact rogue internet pharmacies. Ex. 244 (MCKMDL00336833 at MCKMDL00336847).

(MCKMDL00330924 at 00330926; also stamped MCK-HOI-002-0000001 at 0000003). But, this is not how the program actually operated. Testimony from McKesson's regulatory employees has confirmed the LDMP had no mechanism to block orders once the 8,000 unit threshold was met and while an investigation was ongoing. Ex. 246 (11/28/18 William Mahoney Depo. at 584:11-17). In fact, pharmacy customers were routinely permitted to exceed the 8,000 monthly dosage thresholds prior to a due diligence reviewing being completed by McKesson. (*See e.g.,* Ex. 247, MCKMDL00540033).

McKesson's LDMP did not fare better when it came to identifying suspicious orders either. McKesson has been unable to produce any documentation of true suspicious orders being reported during this time period. Instead, to the extent any orders were reported to DEA during this time period it was only excessive orders meeting the parameters of the Section 55 protocols discussed above.

Additional problems with the LDMP were uncovered during routine auditing of the program. First, it was noted that "it is possible not all of the products containing one of the generic ingredients are included" in the reports generated as part of the LDMP. Ex. 248 (MCKMDL00591949 at MCKMDL00591951). Additionally, the Daily Dosage Summary Report generated under the LDMP was organized by distribution center, and therefore a customer could exceed the monthly 8,000 dosage unit threshold and avoid detection by simply spreading its purchases across multiple distribution centers. Ex. 248 (MCKMDL00591949 at MCKMDL00591951).

(c) McKesson's 2008 Settlement Agreement Confirms the Lack of CSA Compliance under Section 55 and the LDMP.

By 2008, DEA and DOJ felt compelled to punish McKesson for its flagrant non-compliance with the CSA. On May 2, 2008, McKesson entered into a settlement agreement with DEA and DOJ and paid $13,250,000 in fines for numerous violations of the CSA concerning the distribution of opioids. Ex. 249 (MCKMDL00337001). The scope of the violations at issue was sprawling. Ex. 249

(MCKMDL00337001 at MCKMDL00337013 - MCKMDL00337014). Given the national scope of McKesson's SOMs system and the systemic nature of McKesson's CSA violations, the conduct in the 2008 settlement agreement clearly reflects on McKesson's conduct nationwide.

In short, the violations at issue were as egregious as they were widespread. For example, from January 2005 to October 2006 McKesson delivered over 3,000,000 doses of hydrocodone to a single small pharmacy in Baltimore, Maryland while also failing to report any of the orders from that pharmacy as suspicious. Ex. 249 (MCKMDL00337001 at MCKMDL00337013). In a single month, McKesson delivered more than 2 million doses of hydrocodone to seven pharmacies in the Tampa area and failed to report any orders from those pharmacies as suspicious. Ex. 249 (MCKMDL00337001 at MCKMDL00337013). Over a several month period in 2007 McKesson delivered 2.6 million doses of hydrocodone to two Texas pharmacies while failing to report any orders from those pharmacies as suspicious. Ex. 249 (MCKMDL00337001 at MCKMDL00337013). These violations only scratch the surface of the conduct at issue in the 2008 settlement agreement.

In sum, under both Section 55 and the LDMP, McKesson failed to identify and report true suspicious orders and it completely failed to properly investigate or block orders that were flagged under either system. Thus, the conclusion is inescapable that from at least 1997 to May 2008 McKesson failed to meet even the most basic CSA requirements.

2. Even with the Adoption of a New Program in 2008, McKesson Still Failed to Identify and Report Suspicious Orders

(a) McKesson Undertook Significant Efforts To Ensure Its New Program Was Not an Effective Anti-Diversion Program.

In May 2008, McKesson launched the Controlled Substances Monitoring Program (hereinafter "CSMP"). The CSMP continued to apply monthly thresholds, but, unlike the LDMP thresholds, the CSMP's monthly thresholds applied to all opioid products. Thresholds were initially set under the CSMP by reviewing the customer's 12 month purchase history for each drug base code, reviewing the highest month of purchases in that 12 month period, and adding a 10% buffer to that

purchase amount. Ex. 250, 286 (MCKMDL00267635 at MCKMDL00267641; MCKMDL00633917). Thresholds could then be adjusted thereafter through a process referred to as a threshold change request (hereinafter "TCR"). Ex. 250 (MCKMDL00267635 at 00267649).

The CSMP also retained the LDMP's tiered three-level review process, which was triggered once a customer met their monthly threshold. However, the due diligence files produced for Summit and Cuyahoga Counties covering the time span of 2006 to Jan, 1, 2014 include no evidence of a Level 2 or Level 3 review being conducted by McKesson in either county. Ex. 251, Ex. 252, and Ex. 253 (MCKMDL00496212-MCKMDL00496305; MCKMDL00555448-MCKMDL00555744; MCKMDL00568207-MCKMDL00568281). Under the CSMP, McKesson also included a "Know Your Customer" process. Again, however, McKesson's due diligence files produced in this case show that for years this process was very rudimentary in nature and that there were very few substantive investigations being performed. Ex. 251, Ex. 252, & Ex. 253 (MCKMDL00496212-MCKMDL00496305; MCKMDL00555448-MCKMDL00555744; MCKMDL00568207-MCKMDL00568281). Thus, McKesson's due diligence files make clear that McKesson was completely failing to comply with the CSA's investigatory requirements.

With the launch of the CSMP, for the first time McKesson established a process for blocking opioid orders that were identified as suspicious. However, it is clear that the CSMP contained multiple loopholes to ensure as few orders as possible were blocked, thereby ensuring that the controls that were put in place remained completely ineffective.

At the outset of the program, McKesson notified all of its customers they should not expect any change in their ability to order controlled substances under the CSMP. In a document that was disseminated to McKesson's pharmacy customers when introducing them to the CSMP, McKesson stated "[t]his program addresses the DEA's requirements to ensure controlled substances are used in the way they were intended, but it also ensures that you as a McKesson customer can continue with

business as usual." Ex. 254 (MCKMDL00543610 at 00543613) (emphasis added). Given that this document was written just after McKesson entered into a $13.25 million dollar settlement with DOJ for failing to have effective controls against diversion as it pertained to opioid distribution, the message to McKesson's customers should have been that it would be the opposite of business as usual going forward. But McKesson's promise of "business as usual" was backed up by very significant shortcomings in the new program, which ensured that the program would not interfere with opioid sales.

First, although McKesson established thresholds under the CSMP, those thresholds were frequently set far too high to ever be triggered. In fact, in August 2014, DOJ readily pointed out this flaw in McKesson's CSMP. DOJ noted that McKesson's review process under the CSMP was not even triggered until a customer purchased more than 10% of their average[237] month in the prior 12 month period. In addition, these thresholds were set based on purchases from the 2007-2008 time period which DOJ noted was a "year in which McKesson had settled claims because diversion was flourishing in McKesson-supplied pharmacies." Ex. 264 (MCKMDL00409224 at 00409234).

The extremely high thresholds set by McKesson for controlled substances did not go unnoticed within the company. On August 31, 2011, Director of Regulatory Affairs, David Gustin, stated, "I have thought of an area that needs to be tightened up in CSMP and it is the number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy (their threshold) and the amount they really need. (Their current purchases) This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be being used for legitimate purchases.'" Ex. 256 (MCKMDL00507799). Despite Mr. Gustin's concerns,

[237] The reference to the thresholds being set based on the average orders from the prior 12 months also underestimates how McKesson actually set thresholds. According to McKesson's own documents, these thresholds were set based on the highest ordering month from the prior 12 months, not the average month. (*See e.g.,* Ex. 259, MCKMDL00626898).

no serious efforts were undertaken to systematically reduce thresholds until 2015, a full four years later. (*See* Ex. 257, MCKMDL00410744; Ex. 258, MCKMDL00402184).

Second, McKesson routinely increased thresholds without obtaining adequate justification for the increase. In order to have a threshold increased under the CSMP, a customer was supposed to provide documentation supporting a legitimate change in business that warranted the threshold increase. Ex. 250 (MCKMDL00267635 at MCKMDL00267649). However, these requirements were routinely ignored.

For example, in April 2011, David Gustin expressed that McKesson needed to tighten up the process regarding threshold increases because threshold increases were "almost automatic" and being granted for insufficient reasons, like "business increase". Ex. 260 (MCKMDL00507221 at 00507223). Regulatory Affairs Director Tom McDonald reiterated these concerns in July 2012. Mr. McDonald noted that the company was too liberally granting threshold increases without proper documentation and often based only on a claim of business growth by the customer. Ex. 261 (MCKMDL00633455). Mr. Gustin became so concerned about the lack of due diligence being conducted by McKesson that he even noted to other colleagues in regulatory affairs that "[w]e as DRAs need to get out visiting more customers and away from our laptops or the company is going to end up paying the price . . . big time." Ex. 262 (MCKMDL00634329 at 00634331). Another Regulatory Affairs Director, Michael Oriente, responded, "I am overwhelmed. I feel that I am going down a river without a paddle and fighting the rapids. Sooner or later, hopefully later I feel we will be burned by a customer that did not get enough due diligence. I feel it is more of when than if we have a problem rise up." Ex. 262 (MCKMDL00634329 at 00634330-31).

McKesson ultimately acknowledged the problem of deficient due diligence, especially as to threshold increase requests. A November 2013 training deck noted a desire to make threshold change increases "the exception, not the rule" going forward in order to address the lack of due diligence that

had become commonplace at McKesson. Ex. 263 (MCKMDL00516748 at 00516754). The lack of due diligence for threshold increases was also readily apparent to DOJ. In August 2014, DOJ noted that McKesson appeared to be willing to approve threshold increases for opioids for the flimsiest of reasons. Ex. 264 (MCKMDL00409224 at 00409235).

Third, McKesson has a long history of absolute deference to retail national account customers when it comes to threshold increases. McKesson's Senior Director of Distribution Operations, Donald Walker, testified that McKesson did not ask for dispensing data in order to verify the legitimacy of threshold increases for retail national account customers and generally deferred to those customers to decide when it was appropriate for them to get threshold increases for controlled substances. Ex. 265 (See Donald Walker Deposition; Jan 10, 2019; pp. 190-193.). These lax practices resulted in McKesson routinely granting threshold increases to retail national account customers without any apparent due diligence, including many for retail national account customers in Summit and Cuyahoga Counties. *(See e.g.,* Ex. 266, MCKMDL00000497; Ex. 267, MCKMDL00363951; Ex. 268, MCKMDL00574488; Ex. 252, MCKMDL00555448; Ex. 269, MCKMDL00512974; Ex. 270, MCKMDL00628614; Ex. 271, MCKMDL00555473; Ex. 272, MCKMDL00555484; Ex. 273, MCKMDL00555501; Ex. 274, MCKMDL00555506; Ex. 275, MCKMDL00628660; Ex. 253, MCKMDL00568233; Ex. 252, MCKMDL00555480; Ex. 276, MCKMDL00555536).

Fourth, McKesson took affirmative steps to reduce the number of blocked controlled substance orders by warning customers that they were approaching a threshold. This process ensured that customers could seek an increase before McKesson would be forced to block their orders. In fact, this threshold warning system was designed solely to ensure that thresholds could be increased before any sales were lost. In discussing the creation of these reports in October 2006 Sharon Mackarness of McKesson noted, "[w]e are in the business to sell product. If we could produce a report … that warned a customers approach to the threshold, say at 85% of their 10,000 dosages,

work could begin on justifying an increase in threshold prior to any lost sales." Ex. 277 (MCKMDL00543971 at 00543972). These threshold warning reports were utilized for years thereafter to great effect as a preemptive tool to increase thresholds before orders had to be blocked.

Acknowledging the impropriety of providing these warning reports to customers, in November 2013 McKesson announced to its employees a new policy pertaining to threshold warning reports. The presentation states "[w]e are not communicating specific thresholds or providing threshold warning reports. We believe this is a better practice. Thresholds are not intended to allow customers to manage against a number. We strongly believe that customers should exercise their corresponding responsibility one prescription at a time." Ex. 278 (MCKMDL00476786 at 00476791). However, in the following months McKesson was already making exceptions to this newly established policy for customers in Summit and Cuyahoga Counties. (*See e.g.,* Ex. 279, MCKMDL00476692; Ex. 280, MCKMDL00485800). The shift to not providing these warning reports was appropriate and McKesson should have abided by this policy without exception.

The above measures individually and collectively rendered McKesson's CSMP ineffective as an anti-diversion tool. Thus, while the CSMP could have been used as a tool to identify suspicious orders and properly investigate them, significant efforts were undertaken by McKesson to thwart the effectiveness of the system as whole.

McKesson's CSMP also could have been used as a tool to report suspicious orders, but was not used to meet that regulatory requirement until five years after the program was initially launched. For Summit and Cuyahoga Counties, McKesson failed to report a single suspicious order from May 2008 to July 31, 2013. Ex. 281 (MCKMDL00478912). To put those numbers into further context, during that time period McKesson filled approximately 366,000 opioid orders in these two counties. Ex. 282 (MCKMDL00478913). This wholesale failure to report suspicious orders during this time frame is not an anomaly that is restricted to Summit and Cuyahoga Counties. As DOJ recognized as

part of its investigation in 2013 and 2014, there was a "nationwide" and "systemic" failure of McKesson to report suspicious orders and otherwise maintain effective controls against diversion. Ex. 255 (MCKMDL00409453 at 00409454).

The egregiousness of McKesson's failure to report suspicious orders is further supported by the quantity of orders McKesson did report as suspicious once it finally decided to begin engaging in the practice. For example, in 2015 alone, McKesson has acknowledged it reported a total of 230,000 suspicious controlled substance orders nationally. Ex. 283 (McKesson Board of Directors' Response to International Brotherhood of Teamsters at p. 24). Similarly, the rise in suspicious order reports by McKesson in Summit and Cuyahoga Counties beginning in late 2013 cannot be supported by any conclusion except that prior to that time McKesson completely failed to meet its reporting responsibility.

McKesson's failure to report suspicious orders was not accidental or due to a misunderstanding of its regulatory duties. In fact, the term "suspicious" when it came to controlled substances was taboo within the company. At the time McKesson's CSMP was created in 2008 it included a section that advised employees to "[r]efrain from using the word 'suspicious' in communications'" because "[o[nce McKesson deems an order and/or customer suspicious, McKesson is required to act. This means that all controlled substances sales to that customer must cease and the DEA must be notified." Ex. 284 (MCKMDL00518064 at 005118078). This passage demonstrates that McKesson was both fully aware of its regulatory responsibilities and was determined to avoid them at all costs.

(b) McKesson Admitted It Violated the Requirements of the CSA From 2009-2017 as Part of Its 2017 Settlement Agreement with DEA/DOJ.

Ultimately, DEA and DOJ concluded that McKesson's desire for increased sales and customer retention had overridden its obligations to report suspicious orders and jeopardized the health and safety of people around the country. Ex. 264 (MCKMDL00409224 at MCKMDL00409234). DEA

and DOJ described McKesson's due diligence failures as to opioids as both "nationwide" and "systemic". Ex. 255 (MCKMDL00409453 at MCKMDL00409454). As a result of these broad sweeping due diligence failures, McKesson agreed to a $150,000,000 settlement with the DEA and DOJ. Ex. 236 (MCKMDL00355349).

Additionally, as noted above, McKesson accepted responsibility for its nationwide due diligence failures as to opioid distribution spanning 2009 to 2017 and acknowledged that it had fulfilled its obligations under the CSA during this period. Ex. 236 (MCKMDL00355349 at MCKMDL00355352). (2017 Settlement Agreement at p. 5).

It would be expected that such a harsh financial penalty would have dramatically altered McKesson's practices. However, before the ink of the settlement agreement was even dry, McKesson was already re-assuring customers who were concerned that the flow of opioids would be curtailed that it would remain "business as usual" at McKesson. Ex. 285 (MCKMDL00418094). Thus, even after paying a hefty fine for widespread CSA violations, McKesson still indicated it had not learned its lesson.

The overwhelming evidence demonstrates that even with the adoption of the CSMP in 2008 McKesson still failed to properly report, investigate, and block suspicious opioid orders both in Summit and Cuyahoga Counties and nationally. For this reason, summary judgment is appropriate on these points in Plaintiffs' favor.[238]

I. ABDC Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Defendant AmerisourceBergen Drug Corporation ("ABDC") failed to maintain effective controls against diversion because it systematically ignored and violated the "no-shipping duty" articulated in *Masters Pharmaceutical*. AmerisourceBergen consistently shipped orders it identified as

[238] Like other defendants, McKesson attempts to establish the contrary through expert testimony. *See* Ex. 290, Aquino Expert Report. And as is true for other defendants, this expert opinion is inadequate to create a genuine issue of material fact in the face of McKesson's admissions to the DEA.

suspicious before conducting due diligence to determine whether the orders were likely to be diverted into illegal channels.

Prior to 2007, AmerisourceBergen maintained what it referred to as a "*ship and report* process." Ex. 289, ABDCMDL00000101-122, at 109 (emphasis in original). According to Chris Zimmerman, AmerisourceBergen's Senior Vice President of Corporate Security & Regulatory Affairs and Chief Compliance Officer, AmerisourceBergen shipped all orders of controlled substances it identified as suspicious before those orders were ever reported to the DEA. *See* Ex. 291, Zimmerman Deposition I, 108:11-109:16; 110:16-22 ("Q: Just so we have a clear record, the practice was to ship the orders at night, and then the next day any orders that were identified as suspicious were then reported to the DEA; is that correct? A: Correct.") Despite AmerisourceBergen's purported use of a threshold-based system to flag "excessive" (i.e., suspicious) orders that exceeded three-times a particular average sale benchmark, AmerisourceBergen's policy was to ship all "excessive" orders that exceeded that threshold. *Id.*, at 121:7-122:3 ("Any order that was over the threshold amount would be produced [sic] an excessive order report." Q: But it would still be shipped?" A: "The product?" Q: "Yes." A: "Yes.")

AmerisourceBergen's use of a threshold-based system with a three-times multiplier to detect "excessive" orders derived from the DEA's Chemical Handler's Manual's order monitoring system for "listed chemicals." *See* Ex. 291, Zimmerman Deposition I, 131:7-133:22.[239] The Chemical Handler's Manual specifies that "when a regulated person suspects that an order may be intended for illicit purposes, good practice requires that every reasonable effort be made to resolve those suspicions. In addition to making the required reports, the transaction should not be completed until the customer

[239] The DEA Chemical Handler's Manual's reference to a threshold-based system with a three-times multiplier relates to "Listed Chemicals," rather than controlled substances, which are primarily focused on the sale of chemicals used to make illicit methamphetamine. *See* Ex. 292, Chemical Handler's Manual, 2001 Edition, at p. 43 ("Factor equals 3 for C-II and C-III Controlled Substances *Containing List I Chemicals*") (emphasis added). "Suspicious Orders" of Listed Chemicals are defined by 21 U.S.C. § 830(b)(1)(A) as orders of "extraordinary" size. Relying upon a threshold of "extraordinary" size accordingly fails to detect orders of "unusual" size, and is thus not compliant with 21 C.F.R. § 1301.74(b).

is able to eliminate the suspicions. The distributor may have to forego some transactions." Ex. 292 at p. 21. Despite this directive from the Chemical Handler's Manual, AmerisourceBergen did not consider foregoing such transactions, or halting the shipment of suspicious orders, at the time. *See* Ex. 291, Zimmerman Deposition I, 142:16-143:3; 143:9-145:2.

During this timeframe, AmerisourceBergen's policy was to ship all such "excessive" (i.e., suspicious) orders either before, or in the absence of, a due diligence determination that such orders were unlikely to be diverted into illegal channels. Prior to 2007, Eric Cherveny, AmerisourceBergen's Director of Diversion Control and Security, Corporate Security and Regulatory Affairs, was involved with conducting investigations of orders AmerisourceBergen identified as "excessive." *See* Ex. 293, Cherveny Deposition, 277:16-281:7; 298:7-12. Mr. Cherveny, however, admitted that all such due diligence investigations only occurred *after* those orders had already been shipped to AmerisourceBergen's customers:

> Q: Do you recall if one of the things that you were evaluating was whether to fill the order?
>
> A: Well, keep in mind this was a system that we operated that was prior – prior to the system that held orders.
>
> Q: Okay.
>
> A: So this was investigations that occurred after the shipment was already completed.
>
> Q: Okay. So it's your understanding that all these orders and in the possible suspicious order report had already been shipped; is that correct?
>
> A: Yes. Those were – those were orders that have already been shipped. That's correct.

Id., 281:14-282:8; *see also* 337:22-338:2 ("Prior to 2007 orders weren't held when investigation – or when a suspicious order was flagged. *We would conduct those investigations after the fact.*") (emphasis added).

Notwithstanding the fact that AmerisourceBergen's policy was to ship all "excessive" orders prior to conducting any due diligence, the *post-hoc* due diligence AmerisourceBergen did conduct was itself woefully inadequate. In addition to the excessive order reports which included orders that exceeded the relevant threshold, employees in AmerisourceBergen's distribution centers were

provided with guidelines instructing them to report orders that were of unusual size or frequency, or which deviated from the normal ordering pattern. *See* Ex. 291, Zimmerman Deposition I, 118:1-11. AmerisourceBergen placed signs in the distribution center "cages" with the base quantity levels that could be ordered and it was left to a distribution center employee's discretion to determine whether an order was suspicious. *Id*; *see also* Ex. 294, Steve Mays Deposition I, 173:19-174:9. However, AmerisourceBergen did not have any policies or procedures in place to compare its customers' purchase of controlled substances with the average purchases of similarly situated customers. *See* Ex. 295, Steve Mays Deposition II, 68:1-71:23. Nor did AmerisourceBergen have any system in place to monitor its purchasing of Schedule II or III controlled substances as it compared to other types of substances (*id*., 72:1-5), or any system to evaluate the frequency of orders of controlled substances placed by its customers (*id*., 72:22-73:3). Prior to 2007, AmerisourceBergen had no clear hierarchy to establish responsibility for preventing diversion because the company did not even form its Diversion Control Group until after that year. *See* Ex. 296, ABDCMDL00270533.

The year 2007 marks a key shift in AmerisourceBergen's suspicious order monitoring policies, and in particular, its policy to comply with the "no-shipping duty" articulated in *Masters Pharmaceutical*. That year, the DEA initiated an enforcement action against AmerisourceBergen due to its filling and shipping of orders of controlled substances ABDC knew, or should have known, to be suspicious. *See* Ex. 297, ABDCMDL00269383-86 (April 19, 2007 Order to Show Cause and Immediate Suspension of Registration). In its Order to Show Cause, the DEA suspended the registration of AmerisourceBergen's Orlando distribution facility, and specifically found that "Respondent [AmerisourceBergen] has failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1)."[240] *Id*., at ABDCMDL00269383. While the DEA's Order to Show

[240] According to the Order to Show Cause and Immediate Suspension of Registration issued by the DEA, AmerisourceBergen (1) distributed hydrocodone to pharmacies in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers; (2) distributed hydrocodone to pharmacies even though they ordered

Cause singled out the Orlando distribution facility for violations of the "shipping duty," those violations were actually systemic and not limited to the Orlando facility, because AmerisourceBergen maintained national suspicious order monitoring policies and procedures. *See* Ex. 295, Steve Mays Deposition II, 24:18-22; 56:11-17; 57:4-14; 57:16-22; 58:5-15. The policies employed by AmerisourceBergen's Orlando distribution facility that violated the "no-shipping duty" of the Controlled Substances Act were accordingly employed by each of its distribution facilities across the country. *Id.*

As a result of the April 19, 2007 Order to Show Cause, the DEA and AmerisourceBergen entered into a settlement agreement, whereby AmerisourceBergen agreed to overhaul their order monitoring system to stop shipping suspicious orders in violation of the "shipping duty," and to improve their due diligence investigation process:

> THE WITNESS: So through negotiations with DEA and in enhancing our existing order monitoring program that we had in place at the time, DEA wanted us to include a more in-depth due diligence process in addition to ensuring that we only distribute products to licensed individuals. And they also wanted us to modify our suspicious order monitoring program to stop orders that we believed – stop orders that could possibly be suspicious and then to any suspicious – any order we deem suspicious should not be shipped.
>
> Q: Did AmerisourceBergen agree to do that?
>
> A: We modified our program per this agreement, correct.

Ex. 291, Zimmerman Deposition I, 139:16-140:13; *see also* Ex. 298, ABDCMDL00279854-65 (2007 Settlement and Release Agreement).

In 2017, AmerisourceBergen acknowledged this critical shift in their order monitoring policy, noting that as a result of the 2007 negotiations with the DEA, AmerisourceBergen "completely changed the order monitoring process to include holding and not shipping any order that exceeded

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small amounts of other drug products relative to those purchases; (3) distributed hydrocodone to pharmacies much more frequently than AmerisourceBergen's other customers; and (4) shipped to pharmacies that AmerisourceBergen knew or should have known that filled many prescriptions issued by physicians who did not conduct a medical examination of its customers. *See* Ex. 297, ABDCMDL00269383-387.

that pharmacies' peer group threshold," and that "[p]rior to our implementation of the SO [suspicious order] hold, suspicious orders were reported after they had been shipped. Orders are shipped at night, so SO's would not be identified until the next day."[241] Ex. 296, ABDCMDL00270533.

Despite this "complete change" to its order monitoring policy in 2007, however, AmerisourceBergen continued the practice of shipping some orders it identified as suspicious, with little or no documentation as to whether a due diligence investigation was conducted to show such orders were unlikely to be diverted into illegal channels. In 2010, AmerisourceBergen reported *one* suspicious order from Summit County (Order No. CES112610). *See* Ex. 299, ABDCMDL00379674. Despite reporting this suspicious order to the DEA, however, AmerisourceBergen shipped it to its customer, Acme Pharmacy #30, anyway. *See* Ex. 300, ABDCMDL00308070. The only record of AmerisourceBergen's due diligence investigation of this order is the note, "Approved for release per Ed Hazewski." *Id.* Likewise, one of the twelve suspicious orders AmerisourceBergen reported to the DEA in 2012 from Summit County (Order No. 5110197536) was shipped as well. *See* Ex. 299, ABDCMDL00383974. The only record of AmerisourceBergen's due diligence investigation of this order is the note, "Approved for release." *Id.*

The other due diligence policies put in place as a result of the 2007 Settlement Agreement with the DEA also suffered from numerous and critical deficiencies. These defects, along with others, rendered AmerisourceBergen's due diligence program ineffective and toothless. AmerisourceBergen implemented a "Know Your Customer" due diligence policy, consisting of a retail pharmacy questionnaire (the "Form 590"). The Form 590 was supposed to be completed by the AmerisourceBergen sales representative assigned to that particular customer. *See* Ex 291, Zimmerman Dep. I, 199:4-200:21; 201:11-15. This structure created a clear conflict of interest because

[241] Although AmerisourceBergen purported to change components of its order monitoring program in 2007, it continued to implement a threshold-based system based on a three times multiplier. *See* Ex 291, Zimmerman Deposition I, 126:13-127:11. AmerisourceBergen's post-2007 order monitoring program thus suffered from the same fatal deficiency as its pre-2007 program. Both programs were based on the Chemical Handler's Manual's identification of orders of "extraordinary" size, rather than "unusual" size, as is required by 21 C.F.R. § 1301.74(b).

AmerisourceBergen sales representatives, who were responsible for acquiring and maintaining customers, also were in charge of collecting information that would be used against those customers and decrease sales, to halt and investigate suspicious orders of those customers.

Moreover, the Form 590 due diligence process was only used to onboard new customers (rather than to investigate existing customers) (*see* Ex 291, Zimmerman Dep. I, 201:11-24), and it exempted "retail chain pharmacies" (a term broadly defined to include pharmacies with ten or more locations, or any number of locations in more than one state) (*see* Ex. 289, ABDCMDL0000107; *see also* Ex 291, Zimmerman Dep. I, 213:16-214:9).

Finally, in 2016, AmerisourceBergen implemented a "CSRA 590 Validation Project" to "validate that all ABDC customers authorized to purchase controlled substances have the required due diligence documentation in file." Ex. 301 [ABDCMDL00159415]; *see also* Ex. 302, David May Deposition, 272:2-20. However, one year into the project, despite having identified a significant percentage of customer files lacking the requisite due diligence, AmerisourceBergen had only collected the information for about 10% of those files. Ex. 302, David May Dep. 273:18-274:14. By May 29, 2018, AmerisourceBergen estimated that only about 60% of the due diligence deficiencies had been remedied. *Id.*, at 283:24-284:23. Thus, despite a reported shift in its due diligence policies after its 2007 settlement with the DEA, AmerisourceBergen's order monitoring program was a failure both in its implementation, and in its ability to adequately prevent diversion of controlled substances.

The expert report of Robert Buskey submitted by ABDC is not sufficient to create a triable issue of fact concerning ABDC's failure to meet its obligations under the CSA. Ex. 516. Mr. Buskey's Report does not dispute any of the facts discussed above. Rather, Mr. Buskey asserts that ABDC's SOM program was adequate based on an interpretation of the CSA – and in particular, of the reporting and no-shipping duties – at odds with the official pronouncements of the DEA and with the most recent pronouncements and enactments of Congress. *Compare* Buskey Report *with* 21 U.S.C. § 832

("*upon discovering* a suspicious order or series of orders, [the registrant shall] notify the Administrator of the Drug Enforcement Administration. . . .") (emphasis added); Public Law 115-271, § 3272 (recognizing no-shipping duty); Ex. 10, DEA 30(b)(6) Deposition [Prevosnik]; Ex. 4 [Rannazzisi 2006 letter]; Ex. 6 [Rannissizi 2007] Letter; *Southwood Pharmaceuticals*, 72 FR 36487-01; *see also* CSA Duties Mem.[242] The interpretation of the CSA, however, is a legal question for the Court. *See* CSA Duties Mem. Although Mr. Buskey is a former DEA agent, he is not speaking for (and cannot speak for) the DEA and his view of the law is not an official interpretation. That Mr. Buskey's view of the law differs from that of the DEA and Congress (or that ABDC might have been in compliance had the law been what Mr. Buskey believes) does not create a triable issue of *fact* sufficient to defeat summary adjudication that ABDC repeatedly violated the CSA.

J. Prescription Supply Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Prescription Supply, Inc. ("PSI") is a family-run business that has been engaged in the wholesale distribution of pharmaceuticals since 1955.[243] Today, it is a DEA-licensed wholesale distributor involved in pharmaceutical sales across an estimated thirty states.[244] Since the enactment of the CSA in 1971, PSI has understood its duty to maintain effective controls against the diversion of controlled substances, including both its duties to report and halt shipment of suspicious orders.[245]

Prior to 2000, PSI had no written policies and procedures regarding maintaining effective controls against diversion.[246] When PSI did create guidelines in 2000, it did not include a policy to stop

[242] Mr. Buskey opines, for example, that "the DEA has been working on a revised version of the regulation relating to the definition of 'suspicious order' for at least four years. *See* Ex. 516. He does not say that the DEA ever did revise it and Congress has now codified the definition the DEA has used since 1971. *See* 21 U.S.C. § 802 ("suspicious order" includes, but is not limited to, orders of unusual size, unusual frequency, or deviating from normal pattern). Mr. Buskey's statement about what DEA may have been thinking about does not change the law or create a triable issue of fact as to whether ABDC violated the law as it actually was, and is, in effect.

[243] Ex. 303, Deposition of Candace Harbauer, 12:11-18; 19-7:5; 13:12-21.

[244] *Id.* at 15:15-16:4.

[245] Ex. 20, Deposition of 30(b) Representative Thomas Schoen, 56:18-57:17; 59:11-60:2.

[246] Ex. 303, Deposition of Candace Harbauer, 82:10-17.

shipment of suspicious orders.[247] Even after explicit communication from the DEA reiterating wholesale distributors' duty to not ship suspicious orders, PSI never adopted such a policy[248]

Even after PSI adopted a specific policy addressing controlled substances, it did not include any guidelines for determining how to set or raise a customer's threshold or the due diligence required to release a suspicious order.[249] In fact, testimony from the Controlled Substance Handler, James Schoen, indicates that setting and raising thresholds and releasing suspicious orders was entirely up to his discretion.[250] PSI maintained no documentation regarding the basis for his decisions.[251]

In addition to failing to create a system that maintained effective controls against diversion, the undisputed evidence produced by PSI indicates that it violated the CSA by 1) never reporting suspicious orders of opioids to the DEA; and 2) by shipping suspicious orders of opioids without conducting any due diligence to dispel the suspicion of diversion from May of 1997 until 2013.

1. PSI Violated the CSA by Never Reporting a Suspicious Order to the DEA

In 1996, PSI created a suspicious order monitoring system that produced monthly "Suspicious Order Monitoring Reports." These reports, also referred to as "variance reports," indicated whether a pharmacy bought more than the average amount of a product that PSI sold to its customers.[252] PSI sent these reports to the DEA from May of 1997 until 2013.[253]

The Suspicious Order Monitoring Reports did not satisfy PSI's duty to report suspicious orders to the DEA. The Suspicious Order Monitoring Reports were "lookback" reports identifying

[247] See *id.* at 70:4-9 and 94: 22-95:3 (testifying that Plaintiffs have every written policy and procedure of PSI) and 81:4-82:9; 85:10-86:4 (testifying that none of the produced policies or procedures include not shipping a suspicious order)

[248] *Id.* at 107:24-108:8; 109:12-111:15.

[249] Ex. 305, PSI0000653-PSI0000654.

[250] Ex. 306, Deposition of James Shoen, 47:8-16; 42:4; 80:10-81:1.

[251] *Id.* at 20:14-23; 55:7-13.

[252] Ex. 306, Deposition of James Schoen, 45:18-22.

[253] Ex. 306, Deposition of James Schoen, 43:2-8.

orders that had already been shipped the previous month.[254] Suspicious orders must be reported prior to shipment. The DEA explained this to PSI, and other wholesale distributors, by noting that "[f]iling a monthly report of completed transactions ergo excessive purchase report or high unit purchases does not meet the regulatory requirement to report suspicious orders."[255]

PSI recognized that its Suspicious Order Monitoring Reports did not satisfy its reporting duty and has unequivocally admitted that it failed to ever report suspicious orders to the DEA in violation of its obligations under the CSA. PSI's 30(b) representative, Thomas Schoen, testified on behalf of the corporation that the company received suspicious orders as the CSA and federal regulations defined them[256] and that those orders were never reported to the DEA.[257]

Moreover, when PSI's Controlled Substance Handler was asked how many suspicious orders had been reported since 2013, his response was "zero."[258] This testimony is also consistent with the Ohio Board of Pharmacy's letter to PSI in October of 2017 noting that PSI had not reported a suspicious order to the Board during at least the years of 2014, 2015, 2016, and 2017.[259]

It is undisputed that PSI received suspicious orders, but never reported them to the DEA. There are no genuine issues of material fact in this regard and, accordingly, Plaintiffs are entitled to a finding that, as a matter of law, PSI violated the CSA by failing to report suspicious orders to the DEA.

2. PSI Violated the CSA by Shipping Suspicious Orders from May 1997 –2013

As explained above, PSI submitted its Suspicious Order Monitoring Reports to the DEA from May of 1997 until 2013. To the extent PSI intended these reports were to identify and report suspicious

[254] Ex. 307, Deposition of Kirk Harbauer, 98:22-99:2.

[255] Ex. 308, Deposition of Thomas Schoen, Exhibit 17, at 1; Ex. 306, Deposition of James Shoen, 121:17-122:5.

[256] Ex. 20, Deposition of 30(b) Representative Thomas Schoen, 183:23- 184:3.

[257] *Id.* at 150:15-17.

[258] Ex. 306, Deposition of James Schoen, 115:19-116:2.

[259] Ex. 309, PSI0000009.

orders to the DEA, PSI failed to stop shipment of the orders identified therein before reporting them.[260] Because identification of suspicious orders was not done until after shipment, there was no way for PSI to have done any due diligence to ensure the suspicious orders were not likely to be diverted before being released. As stated above, PSI was aware of the "no-shipping requirement," that it required PSI to not ship suspicious orders, and that the requirement had been in place since enactment of the CSA.[261] This conclusively establishes that PSI was violating the CSA by shipping suspicious orders without any due diligence to ensure they would not be diverted from May of 1997 until 2013 and entitles Plaintiffs to judgment as a matter of law in this regard.

K. Walmart Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

As a "self-distributor,"[262] Walmart operated licensed distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances.[263] Prior to 2011, Walmart had not designed any system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations. Then, from 2014 until it stopped self-distributing controlled substances, the systems that Walmart designed and operated to identify suspicious orders of controlled substances did not, and could not, satisfy the identification, reporting or shipping duty. As late as June 2014, Walmart acknowledged that its lack of a compliant monitoring program created the likely risk of severe financial and reputational harm.[264] Indicative of these egregious violations of the CSA, Walmart failed to identify, investigate or report a single order of controlled substances destined for Cuyahoga or Summit Counties prior to April 25,

[260] Ex. 307, Deposition of Kirk Harbauer, 98:22-99:2.

[261] Ex. 20, Deposition of Thomas Schoen, 59:11-60:2.

[262] Walmart pharmacies could also order controlled substances directly from McKesson. Ex. 310, Deposition of Jeff Abernathy ("Abernathy Tr.") 254:2-10. Critically, Walmart's so-called SOMs did not account for these direct orders.

[263] Ex. 311, Deposition of Susanne Hiland ("Hiland Dep. Tr.") 276:4-14.

[264] Exs. 312-13, WMT_MDL_000048100 - WMT_MDL_000048101.

2018. This is despite Walmart shipping numerous suspicious orders to these counties during this time period.[265]

Prior to 2011 there is no documentary evidence that Walmart did anything to meet its statutory obligations.[266] Despite this lack of documentation, Walmart claims that its hourly employees and associates – who were also responsible for filling orders at Walmart Distribution Centers – monitored the orders they were filling for unusual size, pattern, and frequency.[267] Walmart claims that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.[268] But there is no written evidence of such instructions, of any training that would be required to implement such a procedure, or that anyone was ever alerted about an unusual order pursuant to such a procedure. More importantly, this self-serving *post hoc* assertion is directly contradicted by the testimony of a Walmart supervisor Jeff Abernathy *that there was no such policy*.[269] Moreover, Walmart acknowledges that it failed to provide any guidance to the associates in question as to how they should flag an order as suspicious.[270] Instead, Walmart relied on these associates' own subjective personal experiences and memories.[271] Moreover, identifying suspicious orders was not the sole or even the primary task of these employees, but was in addition to their daily responsibilities of packing and shipping orders.[272] To put this in perspective, orders of numerous controlled substances from more than 4,000 pharmacies were filled four days per week, meaning that the only Walmart

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[265] Ex. 314, Plaintiffs' Responses to the Amended and Clarified Discovery Ruling 12 Supplemental Interrogatory Issued to Plaintiffs.

[266] Walmart concedes that its monthly Controlled Drug Stock Exception Reports were not used to monitor daily orders for controlled substances. Ex. 315, Walmart Fed. R. Civ. P. 30(b)(6) Deposition Tr., 221:21-222:5, &295:7-18 (referring to Controlled Drug Stock Exception Reports).

[267] Ex. 310, Abernathy Tr., 24:15 – 25:6.

[268] Ex. 315, Walmart Fed. R. Civ. P. 30(b)(6) Deposition Tr., 170:17-171:3; *see also* Ex. 310, Abernathy Tr., 24:15 – 25:6.

[269] Ex. 310, Abernathy Tr., 42:23 - 43:5; *see also* Ex. 316, Deposition of Ramona Sullins ("Sullins Dep. Tr."), 51:6-61:14.

[270] Ex. 315, Walmart Fed. R. Civ. P. 30(b)(6) Deposition Tr., 214:7-22.

[271] Ex. 315, Walmart Fed. R. Civ. P. 30(b)(6) Deposition Tr.. 52:1-13; 170:17 - 171-6; and 215:18 – 216:23.

[272] Ex. 310, Abernathy Tr.. 24:15 – 25:6.

Distribution Center for Schedule II controlled substances, DC 6045, filled and shipped approximately 40,000 line items of controlled substances per day.[273] Walmart also claims that if an hourly associate alerted management regarding a particular order, the supervisor would investigate with the ordering store to ascertain whether the order was correct.[274] But again, there is no evidence of this ever occurring. There was also no policy to hold an order during the pendency of any so-called "investigation."[275] Indeed, it was not until late 2014 that Walmart's written policies and procedures required a suspicious order to be held until it was verified as appropriate.[276]

Therefore, prior to 2011, the undisputed facts demonstrate that Walmart neither developed, nor maintained a suspicious order monitoring system. Walmart's *post hoc* narrative – that it relied on the personal experience and memories of untrained hourly associates – is farcical and entirely unsupported. Even crediting Walmart's self-serving statements, asking a handful of hourly associates to use their memories to monitor daily orders from 4,000 pharmacies could not and did not satisfy Walmart's identification duty. Additionally, the undisputed evidence shows that even if an hourly employee happened to identify a suspicious order, Walmart's policies and procedures failed to hold shipments of suspicious orders. And, as such, Walmart did not and could not fulfill its shipping duty.

From approximately 2011 until approximately 2015, Walmart implemented a monitoring program that flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders of more than 20 bottles that were 30% higher than a rolling four-week average for that item.[277] As a result, even if an order was more than 30% greater than the four-week average, it

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[273] Ex. 317, WMT_MDL_000006511; *see also* Ex. 316, Sullins Dep. Tr.. 56:6 – 57:5

[274] Ex. 315, Walmart Fed. R. Civ. P. 30(b)(6) Dep. Tr. 242:22-243:15.

[275] *See generally,* Ex. 318, WMT Resp. to Combined Discovery.

[276] *See* WMT Resp. to Combined Discovery, Ex. 318; *See* also WMT_MDL_000054651, Ex. 319 and WMT_MDL_000011107-11109, Ex. 320.

[277] *See* WMT Resps. to Combined Discovery, Ex. 318; and Walmart Fed. R. Civ. P. 30(b)(6) Dep..Tr. 269:8-21; 270:7-17, Ex. 315.

could not draw an alert unless it was also more than 20 bottles (2,000 dosage units).[278] During this time period, orders over 50 bottles were reduced to 50, and then shipped.[279] Walmart's corporate designee testified that it was Mr. Abernathy's responsibility to report suspicious orders to the DEA.[280] Mr. Abernathy, however, confirmed that he never reported such orders to the DEA.[281] Orders that were reduced because they exceeded Walmart's threshold were not reported to the DEA. This testimony confirms that, even if Walmart met its duty to *identify* suspicious orders in this time period, it satisfied neither its reporting duty nor its shipping duty.

In mid-2012 Walmart implemented "hard limits" on opioid orders.[282] Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles (for example, a 40 bottle order was cut to 20 bottles).[283] Orders that were reduced pursuant to these hard limits were neither reported to the DEA, nor held until determined to be appropriate (i.e., the orders shipped). Again, Walmart failed to meet its reporting and shipping duties.

During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles.[284] These orders were reported on a daily basis to Walmart's Home Office for review before shipping by the managers at DC 6045. But while there is evidence of these daily reports being provided to the Home Office, *there is no evidence of any review or any action taking place at the Home Office.* The manager at DC 6045, who often prepared these "Over 20 Reports" testified that he never recalls the Home Office reviewing or holding any order and that the orders that were sent for review would routinely be shipped the same day if he did not hear from the Home Office.

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[278] *See* WMT Resps, to Combined Discovery, Ex. 318.

[279] Abernathy Dep. Tr., 80:2-20, Ex. 310.

[280] Walmart Fed. R. Civ. P. 30(b)(6) Dep. Tr.. 293:7-23, Ex. 315 (confirming that Mr. Abernathy was responsible for reporting suspicious orders to the DEA).

[281] Abernathy Dep. Tr., 152:14-15, Ex. 310 (Q: Did you report those orders [cut 50] to the DEA? A: I did not.)

[282] *See* WMT Resps. to Combined Discovery, Ex. 318.

[283] Abernathy Dep. Tr. 64:24 - 65:22, Ex. 310

[284] *See* WMT Resps. to Combined Discovery, Ex. 318.

More specifically, the "Over 20 Report" was provided to the Home Office in the morning, and if nothing was done by mid-afternoon, the orders were filled and shipped.[285] He could not recall a single instance when an order was reviewed or even held.[286] Further, if an order was reduced, the ordering pharmacy could place an order through McKesson or ABDC.[287] These orders were not monitored by Walmart. In short, Walmart's system permitted orders flagged by the "Over 20 Report" to ship prior to completing the investigation and permitted Walmart stores to evade the restriction by ordering from a different distributor. Thus, even Walmart's "hard-limit" policy failed to satisfy either the reporting or the shipping obligation.

In 2015 Walmart "enhanced" its SOM policy by implementing store-specific thresholds.[288] These thresholds, which were based on the standard deviation of a specific pharmacy's order history for each controlled substance, also included minimum amounts, below which no orders were flagged under any circumstance. Walmart's corporate designee conceded that thresholds were set for business purposes,[289] as opposed to the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). For almost all pharmacies, this minimum remained 2,000 dosage units per week (or 8,000 dosage units per month). Accordingly, even when Walmart implemented a store specific policy that took into consideration a pharmacy's order history, the program was still woefully deficient because a pharmacy could, for example, go from ordering 10 dosage units of Oxycodone 10 mg per month to 7,999 per month without any order being flagged or reviewed.

In sum, the undisputed record evidence shows that prior to 2011 Walmart neither designed, nor implemented a regulatory compliant system to monitor suspicious orders of controlled substances.

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[285] Abernathy Dep. Tr.. 59:6 - 61:21, Ex. 310.

[286] *See* Abernathy Dep. Tr.. 61:14-21; 122:24 -123:23; and 138:1-7, Ex. 310.

[287] Abernathy Dep. Tr.. 254:2-10, Ex. 310.

[288] Walmart Fed. R. Civ. P. 30(b)(6) Dep. Tr. 312:7-18, Ex. 315.

[289] Walmart Fed. R. Civ. P. 30(b)(6) Dep. Tr. 403:24 - 404:5, Ex. 315.

There is no written policy and no documentary evidence of any orders being flagged, held or reviewed.[290] And even crediting the alleged work performed by Walmart's "hourly associates" it is not credible (particularly in light of the volume of orders) to claim that associates could use their experience and memory to determine whether a specific order from a specific pharmacy for a specific controlled substance was potentially suspicious and, therefore, required further investigation. What is more, even if that could have occurred (and there is no credible evidence that it did occur), Walmart's policies and procedures failed to hold shipments of suspicious orders. And, as such, Walmart did not and could not fulfill its shipping duty.

Subsequent to 2011, Walmart's evolving policy was disjointed, inconsistent, unclear, and insufficient. Walmart's witnesses consistently testified that Walmart worked to continuously improve its SOM program. But even when Walmart attempted to put in place a "better," more robust policy to prevent suspicious orders from being shipped, that policy failed due to: (1) the imposition of minimum thresholds, which inherently meant that almost no orders would be flagged, and (2) lack of adherence to the policy by Walmart's responsible personnel. Indeed, as late as 2013 and 2014, Walmart's own documents demonstrate that it did not have a complaint system in place. For example, in a 2013 "Controlled Substance Risk Assessment" presentation, Walmart conceded that it still had not designed (much less operated) a compliant system for suspicious order identification, monitoring, and reporting, and that the date for completion of the same was "TBD."[291] Then in June 2014, Walmart acknowledged it lacked a compliant monitoring program.[292] It also is apparent that Walmart employees either were unaware of, or simply did not comply with, DEA reporting requirements.

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[290] Walmart remains the largest private employer in the United States and the world. The fact that, prior to 2011, it lacked any written policy or procedure (or even training manual) regarding its legal obligations to monitor orders of Opioids from its own pharmacies speaks volumes.

[291] WMT_MDL_000052999, Ex. 321.

[292] WMT_MDL_000048100 - WMT_MDL_000048101, Ex. 322

Walmart pharmacies also had other avenues of ordering various narcotics from third-parties. Walmart did not have access to this information and therefore was incapable of monitoring same.[293] Moreover, it was possible for a Walmart pharmacy to have orders fulfilled by both Walmart and a third-party at the same time. Walmart pharmacies could also order directly from McKesson.[294] In other words, a pharmacy could surpass the threshold by ordering directly from McKesson.

L. Walgreens Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

As both a distributor and a retail pharmacy chain, Walgreens's self-distributed meaning that its distribution "customers" were its own individual Walgreens pharmacies.[295] Walgreens admits that it had the ability to conduct "[d]ata mining… across [its] retail pharmacies to determine the maximum amount that a pharmacy should be allowed to receive…." [296] Though Walgreens had visibility into all of these criteria due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids, relying instead exclusively on the extraordinary volume "three times" formula. As described below, moreover, its programs were wholly inadequate and did not comply with the CSA. Indeed, as part of a settlement with DEA in June 2013, Walgreens admitted that its "suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007."[297] This admission is sufficient for the Court to determine that Walgreens in fact failed to comply with its CSA obligations.[298]

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[293] Abernathy Dep. Tr., 254:2-10, Ex. 310.

[294] Abernathy Dep. Tr., 245:18-21, Ex. 310.

[295] *See e.g.* WAGMDL00757776, Ex. 323.

[296] WAGMDL00757776, Ex. 323.

[297] WAGMDL00490964, Ex. 324

[298] For this reason, any expert opinion to the contrary does not create a genuine issue of material fact.

1. Walgreens Violated the Reporting Requirement and the No-Shipping Requirement with Respect to Orders Listed on Walgreens's Suspicious Control Drug Order report

(a) Walgreens Identified Thousands of Suspicious Orders Based Solely on Extraordinary Volume.

At least as early as 1998,[299] and perhaps as early as 1988,[300] Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012.[301] These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that base number, and then utilized that formula to deem certain orders which were greater than that number to be suspicious.[302] Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two months in a given time period.[303] Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.[304]

Though Walgreens did not utilize any of the other criteria for identifying suspicious orders for these reports, these extraordinarily large orders (three times a historical average) meet the "unusual size" criterion for suspicion set out by the DEA. Utilizing the three times extraordinary size analysis, Walgreens identified thousands of orders placed by pharmacies in the Track One jurisdictions as

[299] E. Bratton 30(b)(6) Deposition at 41-43, Ex. 325; WAGFLDEA00001854, Ex. 326.

[300] US-DEA-00025683, Ex. 327

[301] WAGMDL00709510, Ex. 328; WAGMDL00757762 at 772-773, Ex. 329; WAGMDL00400357, Ex. 330. *See also* Ex. 1, Expert Report of J. Rafalski at p. 125.

[302] WAGMDL00709510, Ex. 328; WAGMDL00757762 at 772-773, Ex. 329; WAGMDL00400357, Ex. 330.

[303] WAGMDL00400357, Ex. 330.

[304] WAGMDL00400357, Ex. 330.

suspicious and listed them on the Suspicious Control Drug Order report.[305] The Suspicious Control Drug Order report was generated on a nationwide basis and each report could be thousands of pages or more in length.[306]

(b) Walgreens Shipped the Orders on the Suspicious Control Drug Orders Reports without Due Diligence Review

Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.[307] Walgreens's shipment of thousands of orders which Walgreens had identified as suspicious based on their extraordinary size without performing due diligence review of the orders violated the "No-Shipping" Requirement.

(c) Walgreens Did Not Report the Orders Listed on the Suspicious Control Drug Order report to the DEA Until After the Orders Shipped.

Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until *after* the orders were already filled and shipped. Walgreens sent the post-shipment Suspicious Control Drug Order report to the DEA on a monthly basis.[308] In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the DEA, as post-2007 orders exceeding the three times multiplier were not reported as suspicious until they exceeded the three times multiplier for more than one month in a given time period.[309] Walgreens's failure to report these orders to the DEA until after they were shipped violated the Reporting Requirement.

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[305] *See* Walgreens's Second Supplemental Responses to Plaintiffs' Combined Discovery Requests at p. 12-13, Ex. 331. ("Walgreens responds that it has produced over 5,000 Suspicious Control Drug Orders (i.e. Suspicious Order Reports) for the Track One jurisdictions.").

[306] *See* E. Stahmann Deposition at 282:8 – 289:1, Ex. 332.

[307] *See* E. Bratton 30(b)(6) Deposition Erratum No. 3, Ex. 333.

[308] *See, e.g.,* E. Stahmann Deposition at 30:14 – 33:5, Ex. 332.

[309] WAGMDL00400357, Ex. 330.

(d) The DEA Found that the Suspicious Control Drug Order Reports Did Not Satisfy Walgreens's Duties under the CSA

In September 2012, the DEA issued an immediate suspension order ("ISO") regarding one of Walgreens three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest."[310] The ISO contained a "statement of [the DEA's] findings regarding the danger to public health or safety"[311] posed by Walgreens's distribution practices. Therein, the DEA specifically considered the Suspicious Control Drug Order reports and made the following findings of fact and conclusions of law[312] regarding the reports and Walgreens's suspicious order monitoring system:

- "[Walgreens's] practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled 'Suspicious Control Drug Orders.'"[313]
- "[The Suspicious Control Drug] reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title [Walgreens's] attached to these reports."[314]
- Upon review of an example of the Suspicious Control Drug Order report for December 2011, "[Walgreens's] suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico."[315]
- Finding that the reports failed to appropriately consider the population and area being served by the pharmacy: "This report from the Jupiter Distribution

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[310] *See* Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices, Ex. 334 (collectively, "Walgreens 2013 MOA") (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at Exhibit B, WAGMDL00387654, Ex. 335 (Letter from Michele Leonhart to Walgreen Company, *Order to Show Cause and Immediate Suspension of Registration* (Sept. 13, 2012), ("ISO")).

[311] 21 C.F.R. § 1301.36(e).

[312] Walgreens does not dispute that ISO contains final findings of fact and conclusions of law. *See* Brief of Petitioner [Walgreen Co.], *Walgreen Co. v. Drug Enforcement Administration, et al.*, CV No. 12-1397, Doc. #1411758 (D.C. Cir. Dec. 26, 2012) (ISO contains "'final determinations, findings, and conclusions' made by DEA") (citing 21 U.S.C. §877).

[313] ISO, WAGMDL00387654 at 657, Ex. 335

[314] ISO, WAGMDL00387654 at WAGMDL00387657, Ex. 335

[315] ISO, WAGMDL00387654 at WAGMDL00387657, Ex. 335

Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area."[316]

- "As made clear in 21 CPR§ 1301.74(b), *Southwood,* and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered,* not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded."[317]
- "Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies. *See* 21 C.F.R. ∫ 1301.74(b); *see also Southwood Pharm., Inc.,* 72 Fed. Reg. 36,487 (2007)."[318]
- "DEA's investigation of [Walgreens] … revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b)."[319]
- "… DEA investigation of [Walgreen's] distribution practices and policies … demonstrates that [Walgreens] has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. ∫∫ 823(b)(l and (e)(l). [Walgreens] failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice."[320]

[316] ISO, WAGMDL00387654 at WAGMDL00387657, Ex. 335

[317] ISO, WAGMDL00387654 at WAGMDL00387657, Ex. 335

[318] ISO, WAGMDL00387654 at WAGMDL00387657, Ex. 335

[319] ISO, WAGMDL00387654 at WAGMDL00387656, Ex. 335

[320] ISO, WAGMDL00387654 at WAGMDL00387656, Ex. 335

- "[Walgreens has not] recognized and adequately reformed the systemic shortcomings discussed herein."[321]
- "[DEA's] concerns with [Walgreens's] distribution practices are not limited to the six Walgreens pharmacies [for which DEA suspended Walgreens's dispensing registration]."[322]

As noted above, the DEA's found Walgreens's failures to fulfill its duties under the CSA were systemic, and its enforcement activity against Walgreens continued. Five months after the issuance of the ISO, in February 2013, the DEA issued subpoenas and an administrative inspection warrant to one of Walgreens other two Schedule II distribution centers, substantially identical to those issued to the first Schedule II distribution center.[323] Walgreens employees promptly made plans in preparation for this distribution center being "shut down" by the DEA, like the first one was.[324] Within weeks of receiving the subpoenas and warrant, Walgreens decided to "discontinue distribution of controlled substances" from that distribution center in order to "eliminate any immediate need for further DEA administrative action."[325] Within months, Walgreens ceased Schedule II controlled substance distribution into CT1, and within a year, Walgreens ceased distribution of Schedule III opioids (HCPs) as well.[326]

Both distribution centers discussed above distributed prescription opioids into CT1.[327]

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[321] ISO, WAGMDL00387654 at WAGMDL00387664, Ex. 335

[322] ISO, WAGMDL00387654 at WAGMDL00387663, Ex. 335

[323] WAGMDL00493694 – 718, Ex. 336.

[324] WAGMDL00477975, Ex. 337; WAGMDL00358471 Ex. 338.

[325] WAGMDL00674280, Ex. 339.

[326] *See, e.g.,* WAGMDL00095936, Ex. 340; WAGMDL00095937, Ex. 341; Ex. 1, Rafalski, Report at p. 132.

[327] *See* Ex. 1, Rafalski Report at p. 114 (The Jupiter, Florida distribution center distributed prescription opioids into CT1 from 2002-2007, and the Perrysburg, Ohio distribution center distributed prescription opioids into CT1 from 2003-2013), Ex. 1.

In June 2013, Walgreens agreed to pay a record $80 million to settle the DEA investigations and actions concerning Walgreens's violations of its CSA duties.[328] As noted above, as part of the settlement, Walgreens admitted that it had failed to comply with its obligations under the CSA.

2. *Walgreens Knew the After the Fact Excessive Purchase Report Did Not Satisfy its Obligations to Identify, Report, and Halt Suspicious Orders*

Walgreens knew that identifying orders based on extraordinary size alone was insufficient to fulfill its duties under the CSA. Walgreens also knew that post-shipment reporting did not satisfy its obligation to report suspicious orders when discovered.

The volume based "three times" method for identifying suspicious orders was facially incomplete, as it failed to account for (a) orders which were of an unusual size but did not meet the three times threshold, (b) orders falling in an unusual pattern, (c) orders placed with unusual frequency, or (d) any other indicia of suspicion. However, Walgreens now takes the position that the DEA ratified use of the post-shipment extraordinary size reports (*i.e.* the Suspicious Control Drug Order reports) to satisfy the Reporting Requirement in full. The evidence does not support that conclusion. There is no evidence that the DEA ever endorsed Walgreens's use of the post-shipment extraordinary size reports as its exclusive or primary SOM system. Instead, the evidence shows that the DEA repeatedly instructed Walgreens that the post-shipment excessive order report did not fulfill Walgreens's Reporting Duties.

In 1988, the DEA specifically advised Walgreens "[t]he submission of a monthly printout of after-the-fact sales does *not* relieve the registrant of the responsibility of reporting excessive or suspicious orders. The[] regulations require that a registrant maintain a system to detect excessive "orders" rather than sales of controlled substances."[329] The DEA further advised Walgreens that,

[328] Settlement and Memorandum of Agreement between the Department of Justice, DEA, and Walgreens Co., with appendices (collectively, "Walgreens 2013 MOA") (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974), Ex. 334

[329] US-DEA-00025683, Ex. 327 (emphasis added).

while "[a]n electronic data system may provide the means and mechanism for complying with the regulations…the system is not complete until the data is carefully reviewed and monitored by the registrant."[330]

Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. [331] As noted above, Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before shipment. [332]

In May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient," and "inadequate" to satisfy Walgreens's duties to identify and report suspicious orders under the CSA.[333] The DEA told Walgreens that, if Walgreens was going to use a formula as part of its SOM system, the "formula should be based on (Size, pattern, frequency)."[334]

Rather than design and operate a comprehensive system to identify suspicious orders, Walgreens merely modified the Suspicious Control Drug Order report formula to be a slightly more focused "three times" analysis, still exclusively focused on volume and still utilizing a three times multiplier based on the DEA's Chemical Handler's Manual's order monitoring system for "listed chemicals."[335]

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[330] US-DEA-00025683, Ex. 327.

[331] WAGMDL00660331, Ex. 342 (In 2010, Walgreens's Regional Supply Chain Vice President stated that, since 1985, his department had not reviewed or contacted anyone regarding the data in the Suspicious Control Drug Report, and the Loss Prevention Department indicated that it was not reviewing the reports, stating that it also was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week.); E Stahmann Dep. at 30:14-33:18; 287:1-289:4, Ex. 332 (One of the managers for Walgreens' Pharmaceutical Integrity Department stated that, when he was with the Loss Prevention Department, he merely burned the reports to CDs and shipped them out, without any review).

[332] *See* E. Bratton 30(b)(6) Deposition Erratum No. 3, Ex. 333.

[333] WAGMDL00709508 Ex. 343; WAGMDL00709510, Ex. 344.

[334] WAGMDL00709508, Ex. 344.

[335] *See* Walgreens's Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Request No. 3, Ex. 331.

Walgreens claims that in 2006 "the Detroit DEA Field Office admonished Walgreens for not basing its reporting of potentially suspicious orders on the 'voluntary formula' found in Appendix E-3" are not supported by the evidence.[336] The documents Walgreens has cited for this proposition do not evidence any such admonition,[337] nor does the record reveal any document which supports this contention. While Walgreens has produced documents indicating that it told the DEA it might use the Chemical Handler's Appendix E-3 formula as a portion of its SOM program,[338] Walgreens has not produced any documents showing that the DEA ratified this approach.

To the contrary, as shown herein, the DEA repeatedly echoed its 1998 instruction that sending the DEA this type of post-shipment report based exclusively on extraordinary size without performing pre-shipment due diligence on the orders did not satisfy the requirements of 21 C.F.R. § 1301.74(b).

Internally, Walgreens's admitted that its pre-2009 suspicious order procedures were insufficient.[339] In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance:

> In our opinion internal controls that ensure compliance with DEA regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions. Specifically, our review found four issues previously cited in the DEA's May 2006 inspection report that are still open. In addition, four issues noted in our previous audit (report dated July 2005) remain un-remediated. Areas requiring the greatest level of improvement are as follows:
>
> DC-wide:
>
> - pseudoephedrine reporting requirements and inventory maintenance

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[336] *See* Walgreens Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3, Ex. 331.

[337] *See* Walgreens Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, Response to Request No. 3, Ex. 331. (citing WAGMDL00709507, at 9510; WAGMDL00387635, at 7636; WAGMDL00395965, at 6010).

[338] See WAGMDL00387642, Ex. 347; WAGMDL00387635, at 7636, Ex. 345; WAGMDL00387651, Ex. 348; see also WAGMDL00395965, Ex. 346;

WAGMDL00400361, Ex. 349.

[339] WAGMDL00757193, Ex. 350.

- suspicious controlled drug order processing and reporting
- controlled drug reporting, specifically receiving record information
- lack of formalized CII controlled substance policies and procedures[340]

The Internal Audit goes on to state that "Walgreens is required to have a process to disclose to the DEA any suspicious orders of controlled substances that deviate from the normal size, pattern, and frequency. Any orders that are deemed to be suspicious are required to be reported to the DEA upon discovery," noting that while "Walgreens produces monthly Suspicious Controlled Drug Orders report," the audit team recommend discussions continue across multiple departments within Walgreens regarding "reporting suspicious control drug orders" and an "Updated Suspicious Control Drug Order Identification Methodology," with an "Estimated Completion Date for the New Reporting" of "June 30 2009."[341]

3. *Walgreens's Additional Systems Did Not Address the Failures in the Suspicious Control Drug Order report to Effectively Control Against Diversion.*

(a) Additional Methods Employed Prior to 2009 Did not Mitigate the Failures of the Suspicious Control Drug Order Report System

Walgreens nominally employed additional procedures within its distribution centers, however these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detected typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."[342]

The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and

[340] WAGMDL00757193, Ex. 350.

[341] WAGMDL00757193, Ex. 350.

[342] WAGMDL00659801, at WAGMDL00659817, Ex. 351.

contact the pharmacy with questions regarding quantities.[343] The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries.[344] The query used to identify excessive orders at the DC level applied equally to controlled substances and items like paper towels, and was never meant to be used for SOM.[345] There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.[346]

The second aspect of this DC level procedures required "pickers", the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.[347] This facet of the DC level policy was also not intended to detect suspicious orders as mandated by the security requirement, but as with the policy in general, merely allowed for the identification of orders potentially entered in error.[348]

The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error.[349] Walgreens admitted this procedure was not intended to detect suspicious orders, but rather was a program designed to detect orders entered in error.[350]

There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's distribution center level policies. There is no evidence these procedures resulted in timely

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[343] WAGMDL00757788, Ex. 352.

[344] WAGMDL00751821 at WAGMDL00751822, Ex. 381.

[345] *See* D. Peterson Deposition at 26:9 - 28:21; 260:15 -262:7, Ex. 353.

[346] *See* Deposition of C. Domzalski, at 165, Ex. 354 (the Chief Audit Executive at Walgreens could not recall any audit department responsibility concerning specific suspicious orders).

[347] WAGMDL00749381, Ex. 355.

[348] *See* D. Bish Deposition 110:16-114:5, Ex. 356.

[349] *See* E. Bratton 30(b)(6) Deposition Erratum No. 1, Ex. 333.

[350] *See* J. Diebert Deposition 129:8-130:1, Ex. 357 and D. Bish Deposition at 72:3-21;502:11-503:10, Ex. 356.

reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

(b) Walgreens's Post-2009 New SOM System Did Not Effectively Control against Diversion

Walgreens did not begin creating a true SOM system until March 2008.[351] The new SOM program was piloted in 2009 and rolled out chain-wide starting in September 2010, in pieces and phases that took more than two years to fully implement.[352] The new SOM program had significant gaps or loopholes.[353] While the new SOM algorithm identified more than 389 pages of suspicious orders thousands of orders per week as of August 2010, it failed capture all the extraordinary orders listed in the Suspicious Control Drug Order reports.[354] Further, for the first few years, the program did not take the orders that Walgreens stores were also placing to outside vendors, like Cardinal and AmerisourceBergen, into account (allowing stores to order opioids from both sources, effectively double dipping), and did not prevent stores from placing an order to an outside vendor if the store attempted to place the order to a Walgreens DC, but was rejected by the new SOM system.[355] The system also allowed Walgreens stores to transfer controlled substances between stores and did not review these transfers in the SOM analysis.[356] Additionally, stores could also place ad hoc "PDQ"

[351] WAGMDL00659801 at 818, Ex. 351; WAGMDL00709395, Ex. 358; WAGMDL00624503, Ex. 359; WAGMDL00667936, Ex. 360.

[352] *See* E. Bratton 30(b)(6) Deposition at 202:16 to 275:8, Ex. 325; WAGMDL00667936 at WAGMDL00667938, Ex. 360; WAGMDL00077016, Ex. 361.

[353] *See* Ex. 362, T. Polster Deposition at 157:9-18.

[354] WAGMDL00660331, Ex. 342

[355] *See* E. Bratton 30(b)(6) Deposition at 258:8-17, Ex. 325; T. Polster Deposition at 144:18 to 145:15, Ex. 362; WAGMDL00245768 at WAGMDL00245769, Ex. 363; *See, e.g.,* WAGMDL00325129 at 130, Ex. 364 (future "enhancements" to SOM system will "identify stores that had order quantity decreased and then placed order to vendor").

[356] WAGMDL00303305 at 306, Ex. 365; *See* E. Bratton 30(b)(6) Deposition at 258:18 to 260:5, Ex. 325; *See also*WAGMDL00303305 at 306, Ex. 365; WAGMDL00700161, Ex. 366.

("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits.[357] Walgreens could even remove a store entirely from SOM review.[358]

Starting in 2010, certain orders which exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out.[359] These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the Reporting Requirement:

> This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders,* not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood,* is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.[360]

From 2009 through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders which exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

(c) Persons Assigned to "Due Diligence" under the new SOM System Did Not Have Resources to Perform Due Diligence and Only Performed Nominal Review On a Small Subset of the Orders, Often Post-Shipment.

Walgreens post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as 20,699 orders for

[357] WAGMDL00705318, Ex. 367.

[358] WAGMDL00492067, Ex. 368.

[359] WAGMDL00077016 at 017, Ex. 361

[360] ISO, WAGMDL00387654 at WAGMDL00387659, Ex. 335

controlled substances were "marked suspicious" by the new algorithm.[361] However, very few of these orders received any review, and any review performed was nominal at best.

Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system.[362] The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week.[363] The second was a Ms. Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only somewhere between 10 to 100 of the thousands of orders which were deemed suspicious under the new algorithm.[364] Walgreens did not provide Ms. Martin access to information about the area the store was serving, the order history for comparable stores, or any other data beyond the sales and order history for that store.[365] If an order did not "make sense" to her based on those limited resources, she said would call the store or district manager or pharmacy supervisor.[366]

In its Discovery Responses, Walgreens points to a series of Ms. Martin's email exchanges and her deposition testimony as exemplars of its due diligence procedures under the post-2009 SOM program.[367] These documents reveal the insufficiency of Walgreens's due diligence measures even under its new and improved SOM system. In a series of emails from January 10-11, 2011, between Ms. Martin and a Walgreens Distribution Center ("DC") employee, the DC notes that "several stores that are ordering huge quantities of 682971 [30 mg oxycodone] on a regular basis," stating regarding

[361] WAGMDL00492171, Ex. 369

[362] E. Bratton 30(b)(6) Deposition (Dec. 16, 2018) at 208:14-211:24; 221:1-23; 256:10-257:7; 266:1-268:2, Ex. 325; Walgreens's Second Amended Objections and Responses to Plaintiffs' First Set of Interrogatories, at p. 12, Ex. 371.

[363] WAGMDL00660331, Ex. 342

[364] Deposition of B. Martin at 69:24 to 71:12. Ex. 370

[365] Deposition of B. Martin at 337:1 to 338:19, Ex. 370.

[366] Deposition of B. Martin at 328:5 to 329:7, Ex. 370

[367] Walgreens's Second Supplemental Responses to Plaintiffs's Combined Discovery Requests at pp. 21-22, Ex. 331.

one store "we have shipped them 3271 bottles [of 30 mg oxycodone] between 12/1/10 and 1/10/11. I don't know how they can even house this many bottles to be honest."[368] Ms. Martin noted that the store had average weekly sales of 36,200 dosage units which was equal to 362 bottles per week, stating "I have no idea where these stores are getting this type of volume. The last pharmacy I was manager at did about 525 rxs/day and we sold about 500 tabs a month (5 bottles)."[369] Ms. Martin then told the DC employee that she could call the district pharmacy supervisor to see if he "may be able to shed some light on the subject."[370]

It appears that this exchange comprised the full extent of the "due diligence" performed on the "huge quantities" of oxycodone identified by Walgreens's DC personnel and was typical of Walgreens's due diligence process.[371] There is no evidence of any actual due diligence beyond this facially insufficient email exchange. Further, despite the fact that questions had been raised about this store ordering volume in January 2011, the very next month, Walgreens filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy, which was located in a town of less than 3,000 people.[372]

In her deposition, Ms. Martin stated that she never even attempted to determine the size of the community that was receiving these "huge quantities" of oxycodone.[373] She further testified that she was not near that store, did not have access to the store's prescriptions or patient information,

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[368] Deposition of B. Martin, Ex. 30 (WAGFLDEA00000846), Ex. 372, 373; *See also* WAGMDL00436802, Ex. 374; WAGFLDEA00000852.

[369] WAGFLDEA00000852, Ex. 375

[370] WAGFLDEA00000852, Ex. 375

[371] B. Deposition of B. Martin at 337:16 to 338:19, Ex. 370; Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658, Ex. 334.

[372] Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658, Ex. 334; B. Deposition of B. Martin at 343:22 to 351:17, Ex. 370.

[373] B. Deposition of B. Martin at 349:7 to 350:12, Ex. 370.

and couldn't take any "direct action."[374] Approximately 18 months after this email exchange, as a result of DEA action, Walgreens agreed to surrender DEA registration for this same store that Ms. Martin reviewed as part of her exemplary "due diligence."[375]

In the ISO regarding the Distribution Center, the DEA found specifically regarding the orders that were the subject of these email exchanges: "Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy."[376] The DEA further found regarding this purported "due diligence," that Walgreens "failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels."[377] DEA noted that "[Walgreens] has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores."[378]

(d) Walgreens's Post-mid-2012 SOM System Similarly Failed to Provide for Pre-Shipment Review, Failed to Report Suspicious Orders, and Still had Insufficient Resources, During the Short Time it was Employed.

In 2012, after the DEA began its investigation into Walgreens's deficient distribution practices, Walgreens "[i]n response, … enhanced its suspicious order monitoring program for controlled substances in an effort to convince DEA that the proposed penalty is excessive and that our new processes will ensure that similar incidents do not recur."[379] In December 2012, this further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be

[374] B. Deposition of B. Martin at 337:16 to 338:19, Ex. 370.

[375] *See* Ex. 334, Walgreens 2013 MOA (WAGMDL00490963-WAGMDL00490978; WAGMDL00387975-WAGMDL00387982; WAGMDL00387653-WAGMDL00387974) at WAGMDL00387658

[376] ISO, WAGMDL00387654 at WAGMDL00387658, Ex. 335

[377] ISO, WAGMDL00387654 at WAGMDL00387658, Ex. 335.

[378] ISO, WAGMDL00387654 at WAGMDL00387658, Ex. 335.

[379] WAGMDL00659270, Ex. 376

investigated" before they could be shipped.[380] Walgreens admitted that yet again it did not have sufficient resources to timely review these orders, noting that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances."[381]

Walgreens admits to failures in suspicious order monitoring prior to 2012, and states that, as a result of the DEA investigation and settlement, it formed the Pharmaceutical Integrity Team, to make sure those types of failures did not happen again.[382] As summarized by one of Walgreens's Pharmaceutical Integrity Managers in August 2013:

> The Controlled Substances Order Monitoring system now in place sets limits for each item based on the chain average for that item for stores of similar size. If a particular store fills more of this item than normal and needs additional product we would need to document the reason and increase via a CSO Override …. The purpose for this is to ensure we have performed adequate review before sending in additional inventory.
>
> The previous system would continue to send additional product to the store without limit or review which made possible the runaway growth of dispensing of products like Oxycodone, that played a roll [sic] in the DEAs investigation of Walgreens.[383]

As part of its new Post-2012 SOM program, Walgreens began to more strictly control the recommended orders and implemented ceilings which more strictly limited stores' ability to exceed the recommended order amounts. However, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.[384]

Walgreens never properly equipped its distribution operations to properly monitor for, report, and halt suspicious orders, or otherwise effectively prevent diversion. When Walgreens's malfeasance

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[380] WAGMDL00659270, Ex. 376

[381] WAGMDL00659270, Ex. 376

[382] S. Mills Deposition at 23:2-24:2, Ex. 377.

[383] WAGMDL00021425, Ex. 378 (emphasis added).

[384] WAGMDL00414048, Ex. 379.

became known, and it was clear Walgreens was going to have to devote significant resources to compliance, Walgreens chose instead to cease controlled substance distribution all together. Walgreens stated that "while the financial impact of no longer…[self distributing] from the Walgreens DCs was taken into consideration, there is a greater risk to the company in fines and loss of licenses if we continue to sell these items in our warehouses."[385]

As noted above, Walgreens stopped distributing Schedule II controlled substances into CT1 in early 2013 and stopped distributing Schedule III opioids (HCPs) into Ohio early 2014.[386]

M. CVS Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

CVS distributed hydrocodone combination products (HCPs) to Summit and Cuyahoga Counties until October 2014, when those products were re-classified as Schedule II in October 2014.[387] As detailed below, through this time period, CVS failed to comply with its obligations under the CSA. CVS also acknowledged, in two separate settlements with DEA, that it failed to meet its compliance obligations under the CSA.[388] CVS-MDLT1-000060805, Ex. 382. These admissions warrant partial summary adjudication that CVS violated the CSA.

From 2006 until early-/mid-2009, CVS did not implement DEA Standard Operating Procedures (SOPs) to identify suspicious orders. In November 2007, for example, CVS was still in the process of writing the suspicious order monitoring section of its standard operating procedures.[389]

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[385] WAGMDL00429246, Ex. 380.

[386] *See, e.g.,* Ex. 340, WAGMDL00095936; Ex. 341, WAGMDL00095937; Ex. 1, Rafalski Report at p. 132.

[387] Expert Report of Craig J. McCann, Ph.D., CFA, Tables 13, 14, 24-43, Ex. 383.

[388] CVS-MDLT1-000060805, Ex. 382; CVS-MDLT1-000060798, Ex. 384. CVS attempts to create an issue of fact on this point by submitting an expert report from Robert Hill offering the opinion that CVS did comply with the CSA. But Mr. Hill's opinions cannot create a factual issue in the face of CVS's own admissions. Moreover, as is the case with other defendants' experts, Mr. Hill appears to apply an interpretation of the CSA at odds with the plain language of the regulations. Mr. Hill contends that "Orders Reflecting an Increase in Prescriptions Written by Legitimate Prescribers Are Not Suspicious." Hill Report at 13. But as discussed above, under § 1301.74, the DEA has defined "suspicious orders" to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency,"21 C.F.R. § 1301.74, and Congress has adopted that definition. 28 U.S.C. § 802. Mr. Hill cannot invent his own definition of "suspicious orders" in order to conclude that CVS met its obligations.

[389] Vernazza Dep. Tr. 214:22-215:10, Ex. 385.

CVS's corporate representative testified that as of December 1, 2017, he did not "believe that there was a suspicious order monitoring policy put into place as of that date."[390] Moreover, the individual listed as the CVS DEA Compliance Coordinator in the Controlled Drug – DEA Standard Operating Procedures Manuals, Amy Propatier, admitted that her title was only for reference and not her real job position, and that the only thing she ever did related to suspicious order monitoring was to update the SOPs manual.[391]

Instead of complying with its obligations under the CSA, during this time period the only system that CVS had to identify orders that might be potentially suspicious were known as "Pickers and Packers" and PDMR ("Viper") Reports. Pickers and Packers worked in the controlled substance cage within the distribution center and they would pick and pack controlled substance orders. CVS's corporate representative testified that CVS did not have any written policies, procedures, or protocols with respect to the Pickers' and Packers' obligations; that CVS did not have a training program to train its Pickers and Packers how to identify unusual orders of size, frequency, or pattern; and there were no formal job requirements to be employed as a Picker and Packer.[392] Instead, the Pickers and Packers would identify orders based on a gut feeling or a crude rule of thumb that essentially can be summarized that they believed the order was simply too large.[393] One of the Pickers and Packers, Ellen Wilson, testified that she was trained by another Picker and Packer in 1996 and that as a rule a Picker and Packer should not send out more than 12 of the small bottles, six of the larger bottles, and two or three of the largest bottes.[394] Wilson used this rule of thumb for her entire career.[395] CVS's

[390] Vernazza Dep. Tr. 221:5-13, Ex. 385.

[391] Propatier Dep. Tr. 79:15-81:2, Ex. 387.

[392] Vernazza Dep. Tr. 197:1-9; 198:3-199:2, Ex. 385.

[393] Wilson Dep. Tr. 61:11-63:14, Ex. 389.

[394] Wilson Dep. Tr. 63:19-64:6, Ex. 389.

[395] Wilson Dep. Tr. 64:4-6, Ex. 389.

"system" predictably flagged few orders: for the Indianapolis distribution center during the period 2006 through 2014, approximately two orders per year were flagged as requiring further approval..[396]

Similarly, the Viper Reports were not an effective SOM process. CVS witnesses testified that these reports were *not* designed to determine suspicious orders.[397] Rather, the Viper Report was an aggregate report that showed shipping versus dispensing to determine whether there was a theft of product.[398] [399] CVS's corporate representative confirmed that that Viper Reports were not reviewed before orders for controlled substances were shipped to CVS's pharmacies.[400]

By April 2009, CVS still did not have a suspicious ordering monitoring section in its SOPs.[401] Around this time, however, CVS began using a computer algorithm that flagged potentially suspicious orders. This system created Item Review Reports ("IRR"). The IRR system was used by CVS until a new system was introduced in 2014. During the period they were in use, IRRs were "the report that would flag orders for additional review."[402] Although IRRs were the primary SOM process, CVS neglected to provide written instructions for how to perform that critical review from its initial use in mid-2009 until February 29, 2012, when the first Work Instructions for Loss Prevention Analyst was instituted, explaining how to perform IRR/SOM analysis. These were the first written instructions by CVS on how to perform an IRR review. CVS's corporate representative testified that "for the most part," if an order was not flagged as suspicious under the IRR system, there would be no due

[396] Hinkle Dep. Tr. 83:23-86:5 Ex. 392.

[397] *See* Vernazza Dep. Tr. 191:18–21, Ex. 385 ("But the point of this was not to produce results for the purposes of determining whether suspicious orders were made and reporting those to the DEA.").

[398] Burtner Dep. Tr. 384:12–21 Ex. 394.

[399] Dugger Dep. Tr. 104:12–22, Ex. 395.

[400] Vernazza Dep. Tr. 191:22-192:12, Ex. 385.

[401] Vernazza Dep. Tr. 235:14-23. Ex. 385.

[402] Vernazza Dep. Tr. 357:10-15, Ex. 385.

diligence of that order.[403] Even then, one CVS employee testified that he investigated 5% or less of the IRR flagged orders.[404]

In addition, during early/mid-2009 to March 2014, CVS's IRRs did not consider outside vendor orders. When performing the calculations of whether an order was suspicious, the IRR did not consider orders delivered to CVS pharmacies by outside vendors.[405] CVS had full access to every order its pharmacies placed to outside vendors but did not incorporate this information in its SOM system. According to CVS policy, whenever an order received due diligence beyond a simple review of the IRR, that review was to be attached to the IRR and documented on the IRR Recap.[406] Review of the IRR Recap Reports shows that few orders actually received additional investigation. For example, the IRR Recap Report from January 2011 to June 2012 shows that CVS investigated only one flagged HCP order placed by a pharmacy in CT1.[407] The IRR Recap Report from February 6, 2013 to December 30, 2013 shows that CVS investigated only one flagged HCP order placed by a pharmacy in CT1.[408] Over a 28-month period, during the height of the opioid crisis, CVS undertook just two investigations of HCP orders in Summit and Cuyahoga Counties. An IRR Recap from January 2, 2014 to February 11, 2014 demonstrates that one store in the Plaintiffs' counties had an order investigated during this time period.[409] In summary, for one half of the country over a period covering twelve days ranging from June 14, 2012 to September 6, 2012, CVS investigated a total of seven control substance orders.[410] In fact, if CVS detected an order to an outside vendor that CVS identified "as an order deviating from normal size, frequency, and/or buying pattern and deemed to

[403] Vernazza Dep. Tr.392:20-393:7, Ex. 385.

[404] Millikan Dep. Tr. 213:0-214:12, Ex. 400.

[405] Burtner Dep. Tr. 284:21 – 285-20, Ex. 394.

[406] Ex. 394, Burtner Dep. Tr. 404: 24–405:10; 474:23–475:8; Hinkle Dep. Tr. 130:8-131:1, *see* Ex. 392.

[407] Burtner Dep. Tr. 488:6–490:4; Ex. 441, *see* Ex. 394.

[408] Burtner Dep. Tr. 485:20–487:1; Ex. 440, *see* 394.

[409] Helfrich Dep. Tr. 142:17–143:22; Ex. 14, *see* Ex. 405.

[410] Burtner Dep. Tr. 340–371; 505; Ex. 500, *see* Ex. 394.

not be for legitimate purposes or are at risk of being diverted [those orders] are ***not*** required to be reported to the DEA."[411]

Rather than devote resources to the IRR process, however, from early/mid-2009 through March 2011, one employee, Henry "John" Mortelliti, "was taking the first pass through the IRR himself."[412] According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on the report warranted further review and due diligence and conduct review and due diligence as he deemed appropriate."[413] During 2009 and 2010, Mr. Mortelliti did not "identif[y] any orders that were deemed suspicious and reported to the DEA."[414] CVS's own internal documentation demonstrates the flawed nature of IRR – and CVS's knowledge of that fact. For example, a document from October 8, 2010 reported that "[t]he current IRR does not provide the proper information to meet the DEA's needs" and the "IRR loses all order history when the info on the item changes causing CVS to be noncompliant with DEA expectations."[415]

N. Rite Aid Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

1. Undisputed Facts Show that Rite Aid Did Not Have a System to Identify and Report Suspicious Orders

Rite Aid violated 21 C.F.R. § 1301.74(b) because it did not have a system to identify and report suspicious orders. Most fundamentally, Rite Aid identified or reported *zero* suspicious orders in the CT1 jurisdictions from 2006-2014. Not only was this during the height of the opioid crisis, Rite Aid made zero reports despite the fact that it had suspicious orders from "pill mill" doctors, suspicious orders evidenced in a DEA settlement, and suspicious orders from Rite Aid's own list of "suspicious

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[411] CVS-MDLT1-000078060-000078069 at 78068, Ex. 407 (emphasis added).

[412] Vernazza Dep. Tr. 365:6-13, Ex. 385. *See also id.* at 368:9-14.

[413] Vernazza Dep. Tr. 371:15-23, Ex. 385.

[414] Vernazza Dep. Tr. 374:7-11, Ex. 385.

[415] CVS-MDLT1-000034175-177, Ex. 411.

prescribers." In fact, the Rite Aid system was designed to avoid identifying suspicious orders through such things as a lack of due diligence on over threshold orders, cutting orders to threshold, and an inability to identify unusual orders at all. To the extent that Rite Aid did internally identify any suspicious orders, it did so only *after* shipment and *never* reported them to DEA.

(a) Rite Aid Distribution System

Rite Aid distributed Schedule III controlled substances (*e.g.*, hydrocodone combination products) to its own Rite Aid stores until late 2014. Rite Aid distributed to the CT1 jurisdictions through its Perryman Distribution Center, a DEA registrant under the CSA.

Rite Aid's practice was fairly simple. *See* Ex. 412 and Ex. 413 [Rite_Aid_OMDL_0014804-Rite_Aid_OMDL_0014874 at 14828; Rite_Aid_OMDL_0015079-0015081]. Rite Aid used a computerized "auto-replenishment system" (ARS) through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center (DC). If the ARS generated an order that was above the universal 5,000 dosage-unit (DU) threshold, the DC employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only "review" of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (*i.e.*, that it was not a "fat-finger" error). If the pharmacy confirmed that the above-threshold order amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were maintained on a handwritten log containing the basic information about the order.

After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. The Rite Aid Asset Protection Department used "key performance indicators" (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft.

(b) Rite Aid Never Identified, Much Less Reported, a Suspicious Order

Most glaringly, Rite Aid *identified zero* suspicious orders for the CT1 jurisdictions between 2006-2014. *See* Response to Plaintiffs' First Set of Combined Discovery Requests to National Retail Pharmacy Defendants at No. 3, Ex. 414. Rite Aid *reported zero* suspicious orders to DEA for the CT1 jurisdictions between 2006-2014. *See id.* at No. 4. In fact, Rite Aid never identified any suspicious orders for anywhere in the United States during the entire time period that Rite Aid distributed controlled substances. Hart Dep. (1/30/19) 114:4-8, Ex. 415 (zero suspicious orders reported to government affairs office between 1995-2014); Wood Dep. 128:18-21, Ex. 416 ("Q. During your time at Rite Aid, no order was ever determined to be suspicious; is that right? A. I don't recall any."); Belli Dep. 114:3-7, Ex. 417 ("Q. To your knowledge during your tenure there, no orders were ever reported as suspicious, correct? . . . THE WITNESS: While I was the -- in my last position there, no.").

The one system at Rite Aid that could identify suspicious orders only identified suspicious orders *after* shipment. Rite Aid testified that the system used by its Asset Protection group (Navicase/Naviscript) routinely analyzed orders through KPIs to determine whether diversion (primarily theft) was occurring. To that end, Rite Aid's 30(b)(6) representative testified as follows:

> THE WITNESS: The asset protection KPIs were utilized to review orders and then lead to diversion cases if there were some issues with it. But they were not used to report suspicious orders.
>
> . . .
>
> Q. Or to identify them. Correct?
>
> . . .
>
> THE WITNESS: They could identify a suspicious order or an order. But if it was out of the norm, they would identify it after it was shipped.

Hart Dep. (1/31/19) 269:10-22, Ex. 418 (emphasis added); see also, Hart Dep. (1/30/19) 188:15-23, Ex. 415 ("We did not use the analytics from asset protection prior to an order being shipped.").

The evidence shows that Rite Aid failed to identify or report any suspicious orders despite the existence of numerous suspicious order in CT1 during 2006-2014. Rite Aid maintained a list of prescribers that Rite Aid explicitly considered "suspicious." Hart Dep. (1/31/19) 163:4-10, Ex. 418.

Yet, Rite Aid did not make any efforts to identify or report any suspicious orders from those suspicious prescribers, even after shipment:

> Q. If a store is filling prescriptions from a prescriber who's been determined to be a suspicious prescriber, does Rite Aid undertake any efforts to identify the orders that come from that store -- during the time when that suspicious prescriber was sending patients to that store, does Rite Aid undertake any effort to identify those orders as suspicious?
>
> MS. McENROE: Objection to form.
>
> THE WITNESS: We do not.
>
> Q. So Rite Aid does not use any of the suspicious prescriber information that it may have collected in determining whether an order from any location is suspicious. Correct?
>
> MS. McENROE: Objection to form.
>
> THE WITNESS: *The order has already been shipped to the store*, so there's – that's not incorporated – the suspicious prescriber isn't incorporated in.
>
> Q. What about when an investigation is going on, does Rite Aid undertake any effort to look at the orders that are continuing to come in as a result of prescriptions being placed through that doctor?
>
> MS. McENROE: Objection to form.
>
> THE WITNESS: We continue to monitor the prescriptions that would be coming in, but we do not consider that a suspicious order to place.

Hart Dep. (1/31/19) 173:1-22, Ex. 418 (emphasis added).

In another example, customers of Dr. Adolph Harper, a notorious convicted pill-mill doctor in CT1, frequented Rite Aid stores to fill their prescriptions. *See* Ex. 419 [MCKMDL00632923 - MCKMDL00632925]. Rite Aid identified zero suspicious orders from Dr. Harper's customers and instead actually requested an *increase* in the amount of CS it was ordering from McKesson specifically to meet the demand from Dr. Harper. Hart Dep. (1/31/19) 186:3-8, Ex. 418; Ex. 419 [MCKMDL00632923 – MCKMDL00632925]. Rite Aid also failed to identify any suspicious orders from stores where its own pharmacists lost their licenses for diverting controlled substances. Hart (1/31/19) 210:13-18, Ex. 418 (never reported any suspicious orders from stores where pharmacist

Marcus Kins was stealing controlled substances); 217:15-23 (never reported any suspicious orders from stores where pharmacist Henry Kozik was stealing controlled substances).

Additionally, Rite Aid entered into a settlement agreement with DEA because "Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose."[416] But, Rite Aid never identified any suspicious orders as a result of the prescriptions that it knew were not issued for a legitimate medical purpose. Hart Dep. (1/31/19) 196:15-20, Ex. 418.

2. Rite Aid's Distribution System Made it Impossible to Identify and Report Suspicious Orders

Rite Aid's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. Rite Aid did could not identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed, was set at of 5,000 DUs, per national drug code (NDC), per order.[417] Hart Dep. (1/31/19) 235:6-19, Ex. 418. Rite Aid did not have procedure that required anyone to report an order that came in over threshold as suspicious. Instead, DC employees would "cut" the order down to the threshold and then ship the order. *Masters*, 861 F.3d at 217–18 (editing orders "subverted the Reporting Requirement" because it is *"attempt* to obtain unusual amounts of a controlled substance" is what is what is suspicious, not what is ultimately shipped). Rite Aid did no due diligence on that came in over the blanket threshold. Chase Dep. at 94:7-18, Ex. 420 ("[W]hen you called the pharmacists or the pharmacies about orders that came in that were above the threshold, you did not ask any other questions besides whether or not the pharmacy needed that particular amount, right? … THE WITNESS: I would only ask them if that order was correct."); Wood Dep. at

[416] Rite Aid Corporation and Subsidiaries Agree to Pay $5 Million in Civil Penalties to Resolve Violations in Eight States of the Controlled Substances Act, available at

https://www.justice.gov/opa/pr/rite-aid-corporation-and-subsidiaries-agree-pay-5-million-civil-penalties-resolve-violations

[417] The only variance to the 5,000 DU threshold was a small number (<10) of Rite Aid stores had higher thresholds. Ex. 421 (Rite_Aid_OMDL_0012503 – Rite_Aid_OMDL_0012505).

144:8-13, Ex. 416 ("Q. When the picker called to verify the ordered quantity, they were just calling to see whether that quantity was correct when it was entered into the system by the pharmacy, right? A. Yes.").

Rite Aid had little to no records about past order history to determine is an order was suspicious. The Perryman DC kept what was called a "Threshold Log," which contained only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. Ex. 422 [Rite_Aid_OMDL_0014035 – Rite_Aid_OMDL_0014036]. But, any the use of the log to potentially identify suspicious orders was only done after the above-threshold orders were cut and shipped. Hart Dep. 171:23-172:3, Ex. 415 (1/30/19) ("Q. To be clear, when you got these threshold logs, these orders reflected in the threshold logs had already been shipped. Correct? A. Yes.").

Rite Aid place the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees who could not do so. According to the DEA coordinator at the Rite Aid's distribution center,

> Q. And the DC center -- the distribution center employees, are they able to identify orders of unusual frequency?
>
> A. As I am understanding it, no.

Wood Dep. 119:2-7, Ex. 416.

> Q. But the distribution center employees would not have an ability to -- have an ability to notice whether the orders coming through the ordering system were deviating from a normal pattern, right?
>
> . . .
>
> THE WITNESS: I believe I stated before, no, I don't believe [the DC employees] would be able to.

Wood Dep. 122:7-17 Ex. 416.

3. Rite Aid Developed, But Never Implemented, a Suspicious Order Monitoring System

Recognized the shortcoming of its distribution system, in 2013, Rite Aid sought to develop a suspicious order monitoring system. Ex. 423 [Rite_Aid_OMDL_0040184-98]. In documenting such efforts, Rite Aid stated as follows:

> *The purpose of this project is to develop effective controls against the diversion of controlled substances* and conduct adequate due diligence to ensure that controlled substances distributed from the Distribution Centers are for legitimate patient needs. Rite Aid must ensure compliance with 21 U.S.C. 823 and/or C.F.R. 1307.74(b) to detect and report suspicious orders of controlled substances through the Distribution Centers.

Id. (emphasis added). In the end, however, Rite Aid never adopted the new SOM because they stopped distributing controlled substances before this system could be implemented.

O. HBC Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

1. The Undisputed Evidence Shows that Defendants Failed to Develop and Maintain a System to Identify Suspicious Orders of Opioids

(a) Defendant HBC Service Company Had No Meaningful System to Identify Suspicious Orders of Opioids

From November 2009 until October 2014, HBC Service Company (HBC) distributed large volumes of controlled substances into Cuyahoga and Summit Counties, including distribution of Hydrocodone Combination Products (HCPs).[418] HBC stopped shipping HPCs in October 2014, when HPCs were reclassified as Schedule II drugs under the Controlled Substances Act.[419] Over nearly a five (5) year period, HBC shipped millions of dosage units of HCPs into Cuyahoga and Summit Counties and the cities therein.[420]

By its own admission, HBC reported only two orders as suspicious, and both orders were for a drug that is not at issue in this litigation.[421] HBC did not report to the DEA a single suspicious order

[418]Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 8: "...[HBC] did not distribute any relevant Schedule III opioids (i.e. those that were later reclassified as Schedule II) until November 2009..."

[419] Id. "...[HBC] stopped distributing relevant Schedule III opioids in October 2014..."

[420] For detailed figures on distribution into relevant jurisdictions, see tables below.

[421] One of those two orders was more than two (2) years after HBC stopped distributing HPCs. *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11, *see* Ex. 424: "On

of HPCs, even though orders of unusual size were regularly being shipped into Cuyahoga and Summit Counties, as explained below. HBC also could not identify a single shipment that was stopped for being suspicious; instead, HBC shipped orders to their customers even if they had been flagged as suspicious. No reasonable fact-finder could conclude that a system with virtually no oversight was adequate. HBC had a patently inadequate system of detection.

(b) HBC had no written SOM policy until August 1, 2014, only two (2) months before it stopped shipping opioids at issue

For nearly the entire five-year period that HBC distributed HCPs, it had no written suspicious order monitoring (SOM) policy. By HBC's own admission, its earliest written SOM policy is dated August 1, 2014.[422] HBC stopped distributing controlled substances at issue in October 2014.[423] HBC, then, operated as a distributor of controlled substances without a written SOM policy for all but two (2) months.

Further, HBC's August 1, 2014 policy does not identify how its SOM system operated, but rather outlines the process for reporting suspicious product orders.[424] This "Inventory Controls Policy" appears to leave most of the responsibility for identifying suspicious orders on parent company Giant Eagle, which also owns all of HBC's customers, Giant Eagle Pharmacies. The policy states:

- HBC Pharmacy group will be contacted by GE Pharmacy team if they suspect any suspicious ordering by a Giant Eagle Pharmacy.
- HBC, as directed by the GE Pharmacy team, will delete or restrict any order that has been identified as suspicious.
- HBC will prepare and communicated any history of suspicious orders to the GE Pharmacy team as requested.

December 5, 2013, HBC identified a suspicious order for buprenorphine 8mg SL tab (the "December 5, 2013 Suspicious Order") and reported the order to the DEA on the same day." The other suspicious order noted on that same page was actually more than two (2) years after HBC stopped distributing drugs at issue in this litigation.

[422] See: Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

[423] Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 8: "..[HBC] stopped distributing relevant Schedule III opioids in October 2014..."

[424] Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

- The GE Pharmacy team will, in conjunction with the HBC Pharmacy information, notify the DEA within the prescribed 3 day time limit.[425]

The policy does not elaborate on how to identify a suspicious order, nor does HBC's warehouse supervisor recall any specific training to identify suspicious orders.[426]

Further, HBC admits in its written discovery responses that it provided no "educational, information and/or other programs to any Customer and/or pharmacy/dispenser that it owns and/or controls or *other Person*, that address diversion, safety, efficacy, misuse and/or prescription of Schedule II Opioids."[427]

HBC thus has failed on its obligation to have an adequate system in place to identify suspicious orders.

(c) HBC first monitored ordering thresholds in October 2013 in a manner it admits was flawed

HBC's attempt to identify orders of unusual size was deeply flawed. On October 15, 2013, after approximately four (4) years of distributing HCPs, HBC finally began to aggregate its customers' controlled substance orders and apply a rudimentary threshold to identify suspicious ordering behavior.[428] From that point until it stopped distributing HCPs, HBC produced a daily spreadsheet that identified shipments, each of which had already been shipped to the pharmacy, that exceeded the chain-wide ordering threshold for the particular drug. HBC admitted that the threshold report kept track of the shipped quantities, not the ordered quantities, further emphasizing the lack of pre-shipping due diligence.[429]

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[425] *Id.*

[426] See Ex. 426, Rogos Dep. Tr. at 71:10-72:2; 77:23-78:13; 141:2-22.

[427] Ex. 427, HBC-4, *HBC Service Company's Supplemental Answers to Plaintiff's First Set of Interrogatories to HBC Service Company*, March 4, 2019, Inter. No. 23, p. 42 (emphasis supplied)("other Person" would include warehouse personnel and other employees)

[428] Ex. 428, Tsipakis Dep. Tr. at 117:18–119:17

[429] Ex. 429, Tsipakis Dep. Tr. 165:14–168:2

HBC's thresholds were also deficient. HBC set thresholds for controlled substances by taking the average amount *all* of its customers ordered and multiplying by three (3). The effect is that when a customer whose orders for a controlled substance in a month exceeded 300% of the average HBC customer, it was flagged on HBC's threshold report.[430] HBC admits setting thresholds by a chain-wide average can result in both false positives (large-volume store consistently orders more than threshold) and false negatives (small-volume stores' relatively large order does not exceed chain-wide threshold).[431] This means that a customer which does a sufficiently large amount of business with HBC might exceed the set threshold. Conversely, a small customer's unusually large order is likely not sufficiently large to clear the 300% average mark, leaving its relatively large orders unscrutinized.

(d) Defendant HBC Failed to Follow Its Own Suspicious Order Policies

HBC's first written SOM policy was adopted on August 1, 2014 and consisted of four short bullet points which were part of a larger policy.[432] This policy relied on Giant Eagle's corporate office to alert HBC if Giant Eagle (GE) pharmacies engaged in suspicious ordering.[433]

The policy also directed that HBC would prepare and communicate any history of suspicious orders to the GE Pharmacy team "as requested," not making such a report a matter of course. The policy then required GE Pharmacy team, *not HBC*, to notify the DEA "with in [sic] the prescribed three day time limit."[434] In this way, HBC's actual policy was to delegate its DEA reporting responsibility to its customers' owner.

HBC's written SOM policy did not result in significant changes to HBC practices. HBC did not report a suspicious order while this written policy was in effect prior to it ceasing to distribute

[430] Ex. 430, Tsipakis Dep. Tr. 118:2–12

[431] Ex. 431, Tsipakis Dep. Tr. 247:8–248:3

[432] Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

[433] *Id.*

[434] *Id.*

controlled substances in October 2014.[435] Giant Eagle did not revise the policy until after HBC stopped distributing controlled substances.[436]

(e) HBC did not systemically investigate the orders its threshold monitoring system did flag

HBC witnesses have acknowledged that they have no recollection of specific investigations, that they had no systematic process in place to investigate flagged orders, and that they have no log or report to document that an investigation occurred for each flagged order.[437] Also, the emails and other documents produced indicated that only a handful of investigations occurred at periodic times and that such investigations were cursory at best.[438]

No reasonable fact-finder could conclude HBC's system was adequate given its lack of documented due diligence on orders identified as suspicious.

2. The Undisputed Evidence Shows that HBC Failed to Report Suspicious Orders in Summit and Cuyahoga Counties

In December 2013, HBC reported its only suspicious order to the DEA during its time shipping controlled substances from November 2009 and October 2014.[439] That suspicious order was for buprenorphine, which is an opioid, but not currently a Schedule 2 controlled substance under the Controlled Substance Act. It is not surprising that HBC did not report any suspicious orders prior to October 2013, because as explained above it did not track its pharmacy-customers' orders against a threshold during that period.

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[435] See Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11 (suspicious order was reported December 2013, before its written policy was in place after August 1, 2014).

[436] See Ex. 432, HBC_MDL00004209, April 2015 "Inventory Control SOM Policy"

[437] Ex. 433, Tsipakis Dep. Tr. at 107:4–108:23; Ex. 434, Mollica Dep. Tr. 220:23–221:6; Ex. 435, Millward Dep. Tr. 179:23–180:8; but see: Ex. 436, Millward Dep. Tr. 257:13–259:8.

[438] Ex. 437, HBC_MDL00039223 (Jan. 10, 2014); Ex. 438, HBC_MDL00058099; Ex. 439, HBC_MDL00090010 (July 8, 2014)

[439] As discussed above, Ex. 424, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 3, p. 11.

3. The Undisputed Evidence Shows that HBC Shipped Orders into Summit and Cuyahoga Counties in Violation of Their CSA Duties

(a) HBC shipped the majority of its CT1 drugs without a threshold monitoring system: 84% of units into Cuyahoga County and 82% of units into Summit County had no threshold order review

Before implementing its first threshold report on October 15, 2013, HBC shipped large amounts of CT1 drugs into Summit and Cuyahoga Counties with no threshold monitoring[440] and with no written SOM policy[441]:

Jurisdiction	Units Shipped (11/12/2009–10/14/2013)	Bates Service
Cuyahoga County	10,684,835	HBC_MDL00189212
Summit County	8,700,931	HBC_MDL00189213

After its threshold program was in place on October 15, 2013, HBC shipped the following amounts of CT1 drugs into Summit and Cuyahoga Counties:

Jurisdiction	Units Shipped (10/15/2013–9/30/2014)	Bates Service
Cuyahoga County	1,940,344	HBC_MDL00189212
Summit County	1,822,912	HBC_MDL00189213

As shown in these tables, HBC shipped 84% of its total CT1 drugs into Cuyahoga County and 82% of its total CT1 drugs into Summit County without a threshold program to monitor suspicious orders.[442]

[440] Ex. 428, Tsipakis Dep. Tr. at 117:18–119:17, first HBC threshold report was on October 15, 2013

[441] HBC's earliest written SOM policy is from August 1, 2014, See: Ex. 425, HBC_MDL00133445 "HBC Service Company Inventory Controls Policy (Version 1)" August 1, 2014

[442] These percentages come from dividing the amount for each county in the first chart by a total of both charts (the sum of which represents the total amount HBC distributed into each county):

Cuyahoga County: 10,684,835 / (10,684,835 + 1,940,344) = 0.8463... or 84% of total distribution into Cuyahoga

Summit County: 8,700,931 / (8,700,931 + 1,822,912) = 0.8267 or 82% of total distribution into Summit

No reasonable fact-finder could determine that HBC fulfilled its duties under the Controlled Substances Act (CSA) while shipping over eighteen million (18,000,000) units of opioids at issue in this case with no written SOM policy. Further, no reasonable fact-finder could conclude that HBC fulfilled its duties under the CSA with its admittedly flawed[443] threshold system and SOM program.[444]

(b) HBC admits it never had the ability to automatically stop its controlled substance shipments which exceeded its set threshold

HBC never had the automated ability to stop shipments which exceeded its established threshold for that controlled substance.[445]

HBC also did not *manually* stop suspicious orders from shipping which had been flagged by its threshold report. HBC admitted that its threshold reports tracked already shipped, not ordered, materials[446] which did not leave an adequate window or process to identify, stop and investigate unusual orders once it became aware of them.

After HBC no longer shipped controlled substances, its parent company Giant Eagle had the opportunity (for its new distribution center) to utilize a third-party system to stop over-threshold orders from shipping. Giant Eagle's Senior Pharmacy Director Adam Zakin declined, claiming it was not worth the expense because the only thing the new system would do was "stop the orders physically if there were a threshold."[447]

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[443] Ex. 430, Tsipakis Dep. Tr. 118:2–12, showing issues which arise using chain-wide ordering averages (not individual pharmacy averages) when setting threshold levels.

[444] As discussed above, *HBC Service Company's Amended Responses to Plaintiffs' (First) Set of Combined Discovery Requests*, December 29, 2018, Request 2, p. 11, showing on no relevant suspicious orders identified.

[445] Ex. 440, Tsipakis Dep. Tr. 201:21-24; 213:8–10, 255:24–256:23.

[446] Ex. 442, Tsipakis Dep. Tr. 141:3–11

[447] Ex. 441, HBC_MDL00028498, 2016.03.29 email: Adam Zakin, Sr. Director, Pharmacy Administration, replying internally regarding a third-party CS ordering system: "Were you not there? At the end of the day, the only thing it did that our current system would not do, was stop the orders physically if there was a threshold."

No reasonable fact-finder could conclude that a distributor who knowingly declined to employ a system which could stop threshold-exceeding orders from shipping has adequately fulfilled its duties under the CSA. [448]

P. DDM Failed to Comply with Its CSA Duties to Maintain Effective Controls against Diversion

Discount Drug Mart ("DDM") is an Ohio-based pharmacy chain with 74 retail stores.[449] DDM shipped Schedule III-V controlled substances from DDM's distribution center located in Medina, Ohio.[450] DDM's shipments included distribution of Hydrocodone Combination Products (HCPs) until approximately 2014, when HCPs were rescheduled to the more restrictive Schedule II .[451] Over nearly a fifteen (15) year period, DDM shipped millions of dosage units of HCPs into Cuyahoga and Summit Counties and the cities therein.[452] From 2006 to 2014 alone, DDM distributed nearly 12 million dosage units to its pharmacies in Cuyahoga County and over 3.4 million dosage units to its pharmacies in Summit County.[453]

DDM never reported a single suspicious order to the DEA, despite the fact that orders of unusual size were regularly distributed by DDM, as explained below. Similarly, DDM could not identify a single order that was halted as suspicious; instead, DDM shipped orders it had flagged as suspicious.

DDM admits it had an obligation to the general public to prevent diversion of opioids.[454] Further, it is undisputed that DDM was legally required to implement a system of effective controls

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[448] The expert opinion of Matthew Greimel is not to the contrary, for two reasons. First, Mr. Greimel does not believe that the no-shipping duty exists, and his opinions are to some extent based on that erroneous legal conclusion. *See* Greimel Report at 11-12. Second, Mr. Greimel reviewed HBC's written policies, but did not review what HBC actually *did*. For that reason, his report creates no genuine issue of fact. Ex. 443.

[449] Ex. 444, Briscoe Dep., at 86.

[450] Ex. 445, Briscoe Dep., at 34-35.

[451] Ex. 446, Briscoe Dep., at 41-42.

[452] Ex. 447, Report of Craig McCann, Appendix 9 at pp 151, 193.

[453] Ex. 448, Report of Craig McCann, Appendix 9 at 3783, 3852.

[454] Ex. 449, Nameth Dep., at 111.

to prevent diversion.[455] Despite this legal duty, DDM had no written policies or procedures regarding suspicious order monitoring.[456] Ultimately, DDM's compliance activity can be boiled down to two reports and activity related to those reports that, according to DDM, were not designed to halt or cease shipment once an order of unusual size was detected.[457] Further, each of these reports was based on a rigid formula,[458] which the DEA has made clear is insufficient.

The "greater than six-week average report," which is also referred to as the "fat finger report,"[459] was implemented by DDM in the early 2000s. This report was generated each time a store placed an order that exceeded its six-week average for a certain item,[460] and thus, identified orders of unusual size,[461] which are by definition "suspicious".[462]

It is undisputed that DDM performed no due diligence on orders identified by the "greater than six-week average report" to determine that the orders were not likely to be diverted into illegal channels.[463] Because orders that appeared on this report were treated as "order errors" rather than as suspicious or potentially suspicious orders,[464] investigation of orders appearing on this report was limited to looking at order history and verifying that the pharmacist intended to order the unusual quantity.[465]

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[455] Ex. 450, Nameth Dep., at 111; Briscoe Dep. At 126-127.

[456] Ex. 451, Strang Dep., at 109, 132, and 194-195; Nameth Dep., at 25, 208, 359; Briscoe Dep., at 244-245.

[457] Ex. 452, Briscoe Dep., at 90-91; 150-151.

[458] Ex. 453, Briscoe Dep., at 147; Nameth Dep., at 192; Strang Dep. At 151.

[459] Ex. 454, Strang Dep., at 64-74.

[460] Ex. 455, Strang Dep., at 64-65.

[461] Ex. 456, Strang Dep., at 146.

[462] Ex. 457, 21 C.F.R. § 1301.74.

[463] Ex. 458, Strang Dep., at 147;

[464] Ex. 459, Strang Dep., at 228-229.

[465] Ex. 460 Strang Dep., at 238.

This report was the only *prospective* component of DDM's suspicious order monitoring policies[466] and therefore the only tool DDM had in place that could have been used to stop the shipment of a suspicious order. However, the report was not created or designated for that purpose[467] and was essentially an inventory management report[468] used to make sure there were no typing errors and that the purchase order matched what the pharmacist intended to order.[469]

Ultimately, despite identifying controlled substance orders that met the criteria to be considered "suspicious," DDM failed to conduct any analysis to determine whether the orders were likely to be diverted from legitimate channels, shipped opioid orders it knew or should have known carried the indicia of likely diversion, and never reported a single suspicious order to the DEA.[470]

The Controlled Substance Monitoring ("CSM") Report, also known as the 12-month report,[471] was generated monthly and identified, for each store, any drug order that exceeded the store's rolling 12-month average by more than 99%.[472] It is undisputed that the CSM Report identified orders of unusual size and orders deviating from a normal pattern.[473] Unlike the six-week average report, this report was generated retrospectively, *i.e.* only *after* orders were shipped.[474] It is also undisputed that DDM did not conduct any analysis to determine whether the orders identified by the CSM Report were likely to be diverted from legitimate channels *prior* to shipping the orders identified by the

[466] Ex. 461, Ratycz Dep., at 98; Strang Dep., at 72, 233-234; Nameth Dep., at 88, 207-208.

[467] Ex. 462 Briscoe Dep., at 63.

[468] Ex. 462, Briscoe Dep., at 63.

[469] Ex. 463, Strang Dep., at 64-65, 72-73; Briscoe Dep., at 141, 150.

[470] Ex. 464, Strang Dep., at 315-317.

[471] An example of the information that would be contained in this report may be found at Ex. 465 ,DDM00053912. See also Nameth Dep., at 210-211.

[472] Ex. 466, Nameth Dep., at 34, 36, 41, 50.

[473] Ex. 467, Nameth Dep., at 152-153.

[474] Ex. 468, Nameth Dep., at 88-89.

report.[475] This report did not identify suspicious orders in a way that would allow DDM to halt them before they were filled.[476]

According to DDM, the opioids purchases of a dozen or more stores appeared on the CSM Report each month.[477] DDM admits that the orders of unusual size that appeared on the CSM Report were not reported to the DEA as suspicious orders.[478] In fact, DDM has never identified or halted a single suspicious order or possible suspicious order, or reported any such orders to the DEA.[479] Further, it is undisputed that the only due diligence performed on orders appearing on the CSM Report was performed after shipment.[480]

In 2013, DDM internally discussed implementing a more aggressive controlled substance monitoring system (handling, dispensing, and reporting) at store and corporate levels.[481] However, no such system was ever put in place.[482] Four years later, in January 2017, DDM internally discussed "developing reporting to help [it] effectively identify outliers and/or suspicious store ordering."[483] To date, nothing has been done.[484] DDM admits that there was no reason that its Controlled Substance Monitoring Report could have been made prospective.[485]

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[475] Ex. 469, Briscoe Dep., at 79

[476] Ex. 470, Nameth Dep., at 124:20-125:2.

[477] Ex. 471, Nameth Dep., at 43, 45.

[478] Ex. 472, Nameth Dep., 80-81, 83; 155, 159.

[479] Ex. 473 Nameth Dep., at 83, 88, 101-102, 155, 210; Strang Dep., at 109, 122, 124, 316-317; Briscoe Dep., at 90, 92; 104.

[480] Ex. 474, Nameth Dep., 167; Briscoe Dep., at 129-130; 155; 164.

[481] Ex. 475, DDM00169025.

[482] Ex. 476, Nameth Dep., at 358.

[483] Ex. 477, DDM00074952. (emphasis added).

[484] Ex. 478, Strang Dep., at 208; Nameth Dep., at 369.

[485] Ex. 479, Nameth Dep., at 121.

CONCLUSION

For the foregoing reasons, this Court should grant Plaintiffs' request for summary adjudication and should find, as a matter of law, that during the period 2000-2016, Purdue, Endo, Teva, Mallinckrodt, J&J, Cardinal, McKesson, ABDC, PSI, Walmart, Walgreens, CVS and Rite Aid were all in violation of their duties, under the Controlled Substances Act to maintain effective controls against diversion, to design and operate a system to identify suspicious orders, to report suspicious orders to the DEA and/or to halt shipment of suspicious orders pending investigation.

Dated: July 2, 2019

Respectfully submitted,

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Attachment

Enforcement Actions the DEA Took vs Distributors and Pharmacies